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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | click or scan EU-EC-10012017174 | | 2022-03-25 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cardiomegaly (n/a - Fatal - **Results in Death**, Life Threatening), Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2 | click or scan EU-EC-10012002415 | | 2022-03-24 | Healthcare Professional | EEA | 0-1 Month | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Transplacental]) |
| 3 | click or scan EU-EC-10011997340 | | 2022-03-24 | Healthcare Professional | Non EEA | 12-17 Years | Female | Death (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4 | click or scan EU-EC-10011989898 | | 2022-03-23 | Healthcare Professional | EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 5 | click or scan EU-EC-10011986904 | | 2022-03-23 | Non Healthcare Professional | EEA | 2 Months - 2 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6 | click or scan EU-EC-10011971165 | | 2022-03-22 | Healthcare Professional | Non EEA | 3-11 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7 | click or scan EU-EC-10011969237 | | 2022-03-22 | Healthcare Professional | EEA | 12-17 Years | Male | Brain injury (n/a - Fatal - **Results in Death**, Life Threatening), Cardio-respiratory arrest (n/a - Recovered/Resolved - Life Threatening), Electrocardiogram QT prolonged (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Loss of consciousness (n/a - Recovered/Resolved - Life Threatening), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 8 | click or scan EU-EC-10011945689 | | 2022-03-20 | Healthcare Professional | EEA | 3-11 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9 | click or scan EU-EC-10011937224 | | 2022-03-18 | Healthcare Professional | Non EEA | 3-11 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10 | click or scan EU-EC-10011935462 | | 2022-03-18 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11 | click or scan EU-EC-10011922459 | | 2022-03-17 | Healthcare Professional | EEA | 0-1 Month | Female | Cerebral haemorrhage neonatal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Foetal exposure timing unspecified (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Inappropriate antidiuretic hormone secretion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Posthaemorrhagic hydrocephalus (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transplacental]) |
| 12 | click or scan EU-EC-10011919415 | | 2022-03-17 | Healthcare Professional | Non EEA | 12-17 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13 | click or scan EU-EC-10011886093 | | 2022-03-14 | Healthcare Professional | EEA | 3-11 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14 | click or scan EU-EC-10011860923 | | 2022-03-11 | Healthcare Professional | Non EEA | 12-17 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15 | click or scan EU-EC-10011841265 | | 2022-03-10 | Healthcare Professional | EEA | 12-17 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16 | click or scan EU-EC-10011831427 | | 2022-03-09 | Healthcare Professional | Non EEA | 3-11 Years | Female | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Epilepsy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Fatal - **Results in Death**), Renal impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Varicella zoster virus infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17 | click or scan EU-EC-10011821153 | | 2022-03-08 | Healthcare Professional | Non EEA | 12-17 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18 | click or scan EU-EC-10011820815 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 3-11 Years | Male | Chills (25min - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19 | click or scan EU-EC-10011812778 | | 2022-03-07 | Healthcare Professional | Non EEA | 12-17 Years | Female | Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20 | click or scan<br>EU-EC-10011797125 | | 2022-03-04 | Non Healthcare Professional | Non EEA | 0-1 Month | Not Specified | Death neonatal (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Unknown - ), Premature baby (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Transplacental]), KEPPRA [LEVETIRACETAM] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Transplacental]) |
| 21 | click or scan<br>EU-EC-10011785504 | | 2022-03-03 | Healthcare Professional | EEA | 0-1 Month | Male | Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hydranencephaly (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Necrotising enterocolitis neonatal (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neonatal seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Perinatal stroke (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental]), [ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, ALUMINIUM, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS (INACTIVATED) ADSORBED] (S - Immunisation - Not applicable - [1d - 1{DF} - Transplacental]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22 | click or scan EU-EC-10011736718 | | 2022-02-28 | Healthcare Professional | Non EEA | 12-17 Years | Female | Adjustment disorder (n/a - Unknown - ), Aortic valve incompetence (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Electrocardiogram ST segment depression (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Panic reaction (n/a - Unknown - ), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sinus rhythm (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23 | click or scan EU-EC-10011731757 | | 2022-02-28 | Healthcare Professional | Non EEA | 12-17 Years | Female | Coma (n/a - Unknown - Other Medically Important Condition), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Metabolic acidosis (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ), Palpitations (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Thirst (n/a - Unknown - ), Weight decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 24 | click or scan EU-EC-10011708631 | | 2022-02-24 | Healthcare Professional | Non EEA | 12-17 Years | Female | Acute respiratory failure (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxic-ischaemic encephalopathy (n/a - Unknown - Other Medically Important Condition), Obesity (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 25 | click or scan EU-EC-10011707898 | | 2022-02-24 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 26 | click or scan EU-EC-10011693464 | | 2022-02-23 | Non Healthcare Professional | EEA | 2 Months - 2 Years | Male | Trisomy 21 (0d - Fatal - **Results in Death**, Congenital Anomaly) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]), [FOLIC ACID] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Transplacental]) |
| 27 | click or scan EU-EC-10011692672 | | 2022-02-23 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 28 | click or scan EU-EC-10011604818 | | 2022-02-14 | Healthcare Professional | EEA | 3-11 Years | Male | Acute respiratory failure (4d - Fatal - **Results in Death**), Diarrhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Irritability (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 29 | click or scan EU-EC-10011546906 | | 2022-02-09 | Non Healthcare Professional | Non EEA | 2 Months - 2 Years | Male | Diet refusal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Emotional distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Failure to thrive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary]) |
| 30 | click or scan EU-EC-10011544194 | | 2022-02-09 | Healthcare Professional | EEA | 12-17 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Respiratory failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 31 | click or scan EU-EC-10011537572 | | 2022-02-08 | Healthcare Professional | EEA | 12-17 Years | Male | Agranulocytosis (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 32 | click or scan EU-EC-10011515940 | | 2022-02-07 | Healthcare Professional | Non EEA | 12-17 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 33 | click or scan EU-EC-10011481066 | | 2022-02-03 | Healthcare Professional | EEA | 12-17 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) |
| 34 | click or scan EU-EC-10011474099 | | 2022-02-02 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 35 | click or scan EU-EC-10011456888 | | 2022-02-01 | Healthcare Professional | Non EEA | 12-17 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 36 | click or scan EU-EC-10011439953 | | 2022-01-31 | Healthcare Professional | EEA | 12-17 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Gastrointestinal hypomotility (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paranoia (n/a - Unknown - Other Medically Important Condition), Pneumococcal sepsis (n/a - Fatal - **Results in Death**), Pneumonia pneumococcal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Substance abuse (7d - Unknown - Other Medically Important Condition), Suicidal ideation (7d - Unknown - Life Threatening), Toxicity to various agents (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]), [CLONAZEPAM] (S - Agitation, Depression - n/a - [n/a - 8mg - n/a]), [LEVOMETHADONE, LEVOMETHADONE HYDROCHLORIDE] (S - n/a - Dose not changed - [n/a - 1mL - n/a]) |
| 37 | click or scan EU-EC-10011422944 | | 2022-01-28 | Healthcare Professional | Non EEA | 12-17 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 38 | click or scan EU-EC-10011420973 | | 2022-01-28 | Healthcare Professional | Non EEA | 12-17 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Head banging (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 39 | click or scan EU-EC-10011401678 | | 2022-01-27 | Healthcare Professional | EEA | 12-17 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 40 | click or scan EU-EC-10011392794 | | 2022-01-26 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 41 | click or scan EU-EC-10011380953 | | 2022-01-25 | Non Healthcare Professional | EEA | 12-17 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 42 | click or scan EU-EC-10011358589 | | 2022-01-22 | Healthcare Professional | EEA | 3-11 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Myocarditis (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular]) |
| 43 | click or scan EU-EC-10011353365 | | 2022-01-21 | Healthcare Professional | EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 44 | click or scan EU-EC-10011323051 | | 2022-01-20 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Cardiac disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 45 | click or scan EU-EC-10011304341 | | 2022-01-18 | Healthcare Professional | Non EEA | 12-17 Years | Male | Cyanosis (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Extensive swelling of vaccinated limb (n/a - Fatal - **Results in Death**), Oedema (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 46 | click or scan EU-EC-10011303586 | | 2022-01-18 | Healthcare Professional | Non EEA | 12-17 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 47 | click or scan EU-EC-10011287208 | | 2022-01-17 | Healthcare Professional | Non EEA | 12-17 Years | Male | C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (10h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cytokine storm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (12h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (12h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (12h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (12h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Serum ferritin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (12h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 48 | click or scan EU-EC-10011286584 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 49 | click or scan EU-EC-10011283421 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 50 | click or scan EU-EC-10011259316 | | 2022-01-13 | Healthcare Professional | Non EEA | 12-17 Years | Female | Chills (n/a - Fatal - **Results in Death**), Pruritus (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 51 | click or scan EU-EC-10011247724 | | 2022-01-13 | Non Healthcare Professional | EEA | 0-1 Month | Male | Ascites (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Foetal malformation (n/a - Fatal - **Results in Death**), Mitral valve atresia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Transplacental]) |
| 52 | click or scan EU-EC-10011231915 | | 2022-01-12 | Non Healthcare Professional | EEA | 12-17 Years | Female | Dyspnoea (35d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 53 | click or scan EU-EC-10011221257 | | 2022-01-11 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Off label use (n/a - Unknown - **Results in Death**), Pharyngitis streptococcal (n/a - Fatal - **Results in Death**), Product administered to patient of inappropriate age (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 54 | click or scan EU-EC-10011191214 | | 2022-01-07 | Non Healthcare Professional | Non EEA | 2 Months - 2 Years | Male | Foetal exposure during pregnancy (n/a - Recovered/Resolved - ), Transposition of the great vessels (176d - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Tricuspid valve incompetence (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Transplacental]) |
| 55 | click or scan EU-EC-10011189943 | | 2022-01-07 | Non Healthcare Professional | EEA | 12-17 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 56 | click or scan EU-EC-10011180703 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Breath sounds (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 57 | click or scan EU-EC-10011178514 | | 2022-01-06 | Healthcare Professional | Non EEA | 12-17 Years | Male | Epistaxis (n/a - Unknown - ), Feeling hot (n/a - Unknown - ), Foaming at mouth (n/a - Unknown - ), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Obstructive airways disorder (n/a - Unknown - ), Off label use (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 58 | click or scan EU-EC-10011172923 | | 2022-01-05 | Healthcare Professional | Non EEA | 12-17 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Head injury (n/a - Unknown - ), Hypotension (n/a - Unknown - Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Liver disorder (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Renal disorder (n/a - Unknown - ), Shock (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (0d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 59 | click or scan EU-EC-10011169392 | | 2022-01-05 | Healthcare Professional | Non EEA | 12-17 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 60 | click or scan EU-EC-10011169374 | | 2022-01-05 | Healthcare Professional | Non EEA | 12-17 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 61 | click or scan EU-EC-10011164976 |  | 2022-01-05 | Healthcare Professional | Non EEA | 12-17 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - ), Meningitis meningococcal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Purpura (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Rash pruritic (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 62 | click or scan EU-EC-10011159955 |  | 2022-01-04 | Healthcare Professional | Non EEA | 0-1 Month | Female | Bedridden (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Unknown - Life Threatening), Respiratory distress (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 63 | click or scan EU-EC-10011151229 |  | 2022-01-04 | Non Healthcare Professional | Non EEA | 3-11 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 64 | click or scan EU-EC-10011121872 |  | 2021-12-30 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Abnormal faeces (n/a - Fatal - **Results in Death**), Anaemia (n/a - Fatal - **Results in Death**), Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Defaecation disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nerve injury (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 65 | click or scan EU-EC-10011120193 |  | 2021-12-30 | Healthcare Professional | Non EEA | 12-17 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 66 | click or scan EU-EC-10011110840 |  | 2021-12-29 | Healthcare Professional | Non EEA | 12-17 Years | Female | Anal sphincter atony (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bladder sphincter atony (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Crepitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyskinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jugular vein distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation immeasurable (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Postictal state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupils unequal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 67 | click or scan EU-EC-10011108137 | | 2021-12-29 | Healthcare Professional | Non EEA | 12-17 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Anaemia (n/a - Fatal - **Results in Death**), Back pain (n/a - Unknown - ), Bone marrow failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Critical illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Haemoglobin decreased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Red blood cell abnormality (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 68 | click or scan EU-EC-10011098855 | | 2021-12-28 | Healthcare Professional | Non EEA | 12-17 Years | Female | Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 69 | click or scan EU-EC-10011096615 | | 2021-12-28 | Healthcare Professional | Non EEA | 12-17 Years | Female | Feeling cold (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 70 | click or scan EU-EC-10011073362 | | 2021-12-24 | Healthcare Professional | Non EEA | 12-17 Years | Female | Brain herniation (2d - Fatal - **Results in Death**, Other Medically Important Condition), Brain injury (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - ), Headache (n/a - Unknown - ), Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 71 | click or scan EU-EC-10011062466 | | 2021-12-23 | Healthcare Professional | EEA | 12-17 Years | Female | Long QT syndrome congenital (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 72 | click or scan EU-EC-10011057758 | | 2021-12-23 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**), Cerebellar haemorrhage (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Subdural haematoma (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 73 | click or scan EU-EC-10011005220 | | 2021-12-20 | Non Healthcare Professional | Non EEA | 12-17 Years | Not Specified | Myocarditis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 74 | click or scan EU-EC-10010994802 | | 2021-12-17 | Healthcare Professional | Non EEA | 12-17 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Nasal congestion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 75 | click or scan EU-EC-10010994770 | | 2021-12-17 | Healthcare Professional | Non EEA | 12-17 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 76 | click or scan EU-EC-10010990331 | | 2021-12-17 | Healthcare Professional | Non EEA | 12-17 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 77 | click or scan EU-EC-10010988637 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 78 | click or scan EU-EC-10010986554 | | 2021-12-16 | Healthcare Professional | Non EEA | 3-11 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 79 | click or scan EU-EC-10010982581 | | 2021-12-16 | Healthcare Professional | EEA | 2 Months - 2 Years | Female | Foetal death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 80 | click or scan EU-EC-10010968305 | | 2021-12-15 | Healthcare Professional | Non EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 81 | click or scan EU-EC-10010963145 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 12-17 Years | Not Specified | Accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 82 | click or scan EU-EC-10010960337 | | 2021-12-15 | Healthcare Professional | Non EEA | 12-17 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 83 | click or scan EU-EC-10010958355 | | 2021-12-15 | Healthcare Professional | Non EEA | 12-17 Years | Female | Chills (1h - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (1h - Recovered/Resolved - ), Pain (n/a - Unknown - ), Pyrexia (1h - Recovered/Resolved - ), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 84 | click or scan EU-EC-10010923828 | | 2021-12-10 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 85 | click or scan EU-EC-10010922347 | | 2021-12-10 | Non Healthcare Professional | EEA | 0-1 Month | Not Specified | Heart disease congenital (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transplacental]) |
| 86 | click or scan EU-EC-10010889205 | | 2021-12-08 | Healthcare Professional | Non EEA | 12-17 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 87 | click or scan EU-EC-10010878803 | | 2021-12-07 | Healthcare Professional | Non EEA | 2 Months - 2 Years | Not Specified | Foetal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Stillbirth (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 88 | click or scan EU-EC-10010868932 | | 2021-12-06 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 89 | click or scan EU-EC-10010868257 | | 2021-12-06 | Non Healthcare Professional | EEA | 12-17 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 90 | click or scan EU-EC-10010835805 | | 2021-12-02 | Healthcare Professional | EEA | 12-17 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 91 | click or scan EU-EC-10010826185 | | 2021-12-02 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 92 | click or scan EU-EC-10010696156 | | 2021-11-19 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - **Results in Death**), Product administered to patient of inappropriate age (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 93 | click or scan EU-EC-10010681141 | | 2021-11-18 | Healthcare Professional | Non EEA | 0-1 Month | Male | Death neonatal (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 94 | click or scan EU-EC-10010672595 | | 2021-11-17 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 95 | click or scan EU-EC-10010661990 | | 2021-11-16 | Healthcare Professional | EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 96 | click or scan EU-EC-10010660918 | | 2021-11-16 | Healthcare Professional | Non EEA | 12-17 Years | Female | Cataract cortical (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial pressure increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 97 | click or scan EU-EC-10010650054 | | 2021-11-15 | Healthcare Professional | Non EEA | 12-17 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 98 | click or scan EU-EC-10010620335 | | 2021-11-11 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Bronchospasm (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 99 | click or scan EU-EC-10010607769 | | 2021-11-10 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 100 | click or scan EU-EC-10010546914 | | 2021-11-03 | Healthcare Professional | EEA | 0-1 Month | Not Specified | Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Limb malformation (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - n/a]) |
| 101 | click or scan EU-EC-10010535956 | | 2021-11-02 | Healthcare Professional | EEA | 12-17 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Hypoventilation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nasopharyngitis (n/a - Not Recovered/Not Resolved - ), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 102 | click or scan EU-EC-10010520787 | | 2021-11-02 | Non Healthcare Professional | EEA | 0-1 Month | Male | Metabolic syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 2 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 103 | click or scan EU-EC-10010493474 | | 2021-10-29 | Healthcare Professional | EEA | 12-17 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 104 | click or scan EU-EC-10010477762 | | 2021-10-28 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Ovarian enlargement (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 105 | click or scan EU-EC-10010391161 | | 2021-10-21 | Healthcare Professional | EEA | 12-17 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - Contraception - Drug withdrawn - [n/a - 21{DF} - Oral]) |
| 106 | click or scan EU-EC-10010391147 | | 2021-10-21 | Healthcare Professional | EEA | 0-1 Month | Male | Foetal death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Transplacental]) |
| 107 | click or scan EU-EC-10010376118 | | 2021-10-20 | Healthcare Professional | Non EEA | 12-17 Years | Male | Brain herniation (n/a - Unknown - Other Medically Important Condition), Brain oedema (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastric disorder (n/a - Unknown - ), Gastric ulcer (n/a - Unknown - Other Medically Important Condition), Gastritis erosive (n/a - Unknown - Other Medically Important Condition), Myocardial bridging (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 108 | click or scan EU-EC-10010371169 | | 2021-10-20 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 109 | click or scan EU-EC-10010360356 | | 2021-10-19 | Non Healthcare Professional | EEA | 12-17 Years | Male | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 110 | click or scan EU-EC-10010338768 | | 2021-10-15 | Non Healthcare Professional | EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 111 | click or scan EU-EC-10010286244 | | 2021-10-11 | Healthcare Professional | EEA | 0-1 Month | Not Specified | Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly), Limb malformation (105d - Fatal - **Results in Death**, Congenital Anomaly), Limb reduction defect (105d - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 112 | click or scan EU-EC-10010269731 | | 2021-10-08 | Healthcare Professional | Non EEA | 0-1 Month | Not Specified | Death neonatal (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 113 | click or scan EU-EC-10010236495 | | 2021-10-06 | Healthcare Professional | EEA | 12-17 Years | Female | ADAMTS13 activity decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 114 | click or scan EU-EC-10010217879 | | 2021-10-05 | Non Healthcare Professional | EEA | 12-17 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 115 | click or scan EU-EC-10010210329 | | 2021-10-04 | Healthcare Professional | EEA | 0-1 Month | Female | Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**), Neonatal anoxia (n/a - Fatal - **Results in Death**), Neonatal multi-organ failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 116 | click or scan EU-EC-10010193681 | | 2021-10-01 | Healthcare Professional | Non EEA | 12-17 Years | Male | Cerebral haemorrhage (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ventricular rupture (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 117 | click or scan EU-EC-10010127333 | | 2021-09-24 | Healthcare Professional | Non EEA | 12-17 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 118 | click or scan EU-EC-10010093552 | | 2021-09-22 | Non Healthcare Professional | EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 119 | click or scan EU-EC-10010073173 | | 2021-09-20 | Healthcare Professional | EEA | 2 Months - 2 Years | Not Specified | Foetal exposure during pregnancy (14d - Fatal - **Results in Death**), Heart disease congenital (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 120 | click or scan EU-EC-10010010062 | | 2021-09-15 | Healthcare Professional | Non EEA | 12-17 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 121 | click or scan EU-EC-10010007112 | | 2021-09-15 | Healthcare Professional | Non EEA | 12-17 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 122 | click or scan EU-EC-10009989870 | | 2021-09-14 | Non Healthcare Professional | EEA | 0-1 Month | Not Specified | Anencephaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure before pregnancy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [78d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 123 | click or scan EU-EC-10009864895 | | 2021-09-02 | Healthcare Professional | EEA | 12-17 Years | Male | Septic shock (26d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 124 | click or scan EU-EC-10009860999 | | 2021-09-01 | Healthcare Professional | EEA | 12-17 Years | Male | Leukaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 125 | click or scan EU-EC-10009817992 | | 2021-08-27 | Healthcare Professional | EEA | 12-17 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 126 | click or scan EU-EC-10009815542 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 12-17 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 127 | click or scan EU-EC-10009789688 | | 2021-08-25 | Non Healthcare Professional | Non EEA | 0-1 Month | Not Specified | Foetal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Hydrocephalus (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Transplacental]) |
| 128 | click or scan EU-EC-10009747324 | | 2021-08-20 | Healthcare Professional | EEA | 12-17 Years | Male | Disseminated intravascular coagulation (23h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (23h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary haemorrhage (23h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (23h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (23h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 129 | click or scan EU-EC-10009743215 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 130 | click or scan EU-EC-10009631536 | | 2021-08-09 | Non Healthcare Professional | Non EEA | 0-1 Month | Not Specified | Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Premature baby (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR]) |
| 131 | click or scan EU-EC-10009528413 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 132 | click or scan EU-EC-10009340528 | | 2021-07-12 | Healthcare Professional | EEA | 0-1 Month | Male | Antibody test abnormal (n/a - Fatal - **Results in Death**), Isoimmune haemolytic disease (n/a - Fatal - **Results in Death**), Rhesus antibodies positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 133 | click or scan EU-EC-10009321122 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 134 | click or scan EU-EC-10009320743 | | 2021-07-09 | Healthcare Professional | EEA | 0-1 Month | Male | Growth retardation (n/a - Fatal - **Results in Death**), Premature delivery (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]), [ATENOLOL, ATENOLOL BP] (S - Cardiac valve disease - Not applicable - [n/a - n/a - Oral]) |
| 135 | click or scan EU-EC-10009305404 | | 2021-07-08 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 136 | click or scan EU-EC-10009213103 | | 2021-06-30 | Healthcare Professional | EEA | 0-1 Month | Female | Foetal death (n/a - Fatal - **Results in Death**), Generalised oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Transplacental]) |
| 137 | click or scan EU-EC-10009206279 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 2 Months - 2 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during breast feeding (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Transmammary]) |
| 138 | click or scan EU-EC-10009129480 | | 2021-06-24 | Non Healthcare Professional | Non EEA | 12-17 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - ), Completed suicide (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Feeling abnormal (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Hypersomnia (n/a - Not Recovered/Not Resolved - ), Illness (n/a - Not Recovered/Not Resolved - ), Lethargy (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular - More in ICSR]) |
| 139 | click or scan EU-EC-10008822508 | | 2021-05-28 | Healthcare Professional | Non EEA | 0-1 Month | Male | Death (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Meconium aspiration syndrome (n/a - Unknown - Other Medically Important Condition), Premature baby (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR]) |
| 140 | click or scan EU-EC-10008557015 | | 2021-05-06 | Healthcare Professional | EEA | 12-17 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 141 | click or scan EU-EC-10008490019 | | 2021-04-30 | Healthcare Professional | Non EEA | 12-17 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 142 | click or scan EU-EC-10012022237 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 143 | click or scan EU-EC-10012022144 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 144 | click or scan EU-EC-10012022137 | | 2022-03-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Recovered/Resolved - ), Dizziness (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 145 | click or scan EU-EC-10012021995 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebellar embolism (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 146 | click or scan EU-EC-10012021994 | | 2022-03-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 147 | click or scan EU-EC-10012021990 | | 2022-03-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thunderclap headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 148 | click or scan EU-EC-10012021953 | | 2022-03-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 149 | click or scan EU-EC-10012021902 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 150 | click or scan EU-EC-10012018962 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diabetes insipidus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Generalised oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immune system disorder (n/a - Unknown - Other Medically Important Condition), Liver disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphocytic infiltration (n/a - Fatal - **Results in Death**), Multi-organ disorder (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Polyuria (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Renal impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 151 | click or scan EU-EC-10012018540 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 152 | click or scan EU-EC-10012018068 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 153 | click or scan EU-EC-10012018067 | | 2022-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 154 | click or scan EU-EC-10012017327 | | 2022-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chills (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .25mL - Intramuscular]) |
| 155 | click or scan EU-EC-10012017186 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Body temperature increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Heat illness (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 156 | click or scan EU-EC-10012017178 | | 2022-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bedridden (n/a - Unknown - ), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatosplenomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Mitral valve incompetence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 157 | click or scan EU-EC-10012017168 | | 2022-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**), Cyanosis (1d - Fatal - **Results in Death**), Depressed level of consciousness (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 158 | click or scan EU-EC-10012015370 | | 2022-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Pallor (n/a - Unknown - ), Peripheral embolism (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Unknown - ), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Truncus coeliacus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 159 | click or scan EU-EC-10012015365 | | 2022-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anal incontinence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Biliary tract infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Liver disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 160 | click or scan EU-EC-10012015347 | | 2022-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Disease progression (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 161 | click or scan EU-EC-10012014936 | | 2022-03-25 | Healthcare Professional | EEA | 65-85 Years | Female | Bacteraemia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 162 | click or scan EU-EC-10012014878 | | 2022-03-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Limbic encephalitis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 163 | click or scan EU-EC-10012014869 | | 2022-03-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (n/a - Unknown - Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Unknown - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 164 | click or scan EU-EC-10012014859 | | 2022-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .25mL - Intramuscular]) |
| 165 | click or scan EU-EC-10012014846 | | 2022-03-25 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 166 | click or scan EU-EC-10012014404 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (0d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 167 | click or scan EU-EC-10012014041 | | 2022-03-25 | Healthcare Professional | EEA | 18-64 Years | Male | Immune thrombocytopenia (35d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 168 | click or scan EU-EC-10012013099 | | 2022-03-25 | Healthcare Professional | EEA | 18-64 Years | Female | Basilar artery thrombosis (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebellar infarction (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Locked-in syndrome (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 169 | click or scan EU-EC-10012012591 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 170 | click or scan EU-EC-10012012190 | | 2022-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure increased (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 171 | click or scan EU-EC-10012011753 | | 2022-03-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 172 | click or scan EU-EC-10012010922 | | 2022-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 173 | click or scan EU-EC-10012009705 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatitis fulminant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Livedo reticularis (n/a - Unknown - Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 174 | click or scan EU-EC-10012009636 | | 2022-03-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain lower (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 175 | click or scan EU-EC-10012008902 | | 2022-03-25 | Healthcare Professional | EEA | 65-85 Years | Male | Ataxia (48d - Fatal - **Results in Death**), Confusional state (48d - Fatal - **Results in Death**), Dysphagia (48d - Fatal - **Results in Death**), Dystonia (48d - Fatal - **Results in Death**), Hallucination (48d - Fatal - **Results in Death**), Myoclonus (48d - Fatal - **Results in Death**), Nervous system disorder (48d - Fatal - **Results in Death**), Prion disease (48d - Fatal - **Results in Death**), Psychomotor hyperactivity (48d - Fatal - **Results in Death**), Respiratory failure (48d - Fatal - **Results in Death**), Sopor (48d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 176 | click or scan EU-EC-10012008869 | | 2022-03-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (115d - Fatal - **Results in Death**), Anaemia (115d - Fatal - **Results in Death**), Cardiac failure (115d - Fatal - **Results in Death**), Coagulopathy (115d - Fatal - **Results in Death**), Dysphagia (115d - Fatal - **Results in Death**), Faecaloma (115d - Fatal - **Results in Death**), Hyperuricaemia (115d - Fatal - **Results in Death**), Intestinal ischaemia (115d - Fatal - **Results in Death**), Leukocytosis (115d - Fatal - **Results in Death**), Pain in extremity (115d - Fatal - **Results in Death**), Syncope (115d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 300uL - Intramuscular]) |
| 177 | click or scan EU-EC-10012008190 | | 2022-03-24 | Healthcare Professional | EEA | 18-64 Years | Female | Encephalitis (n/a - Fatal - **Results in Death**), Infection (n/a - Unknown - ), Pneumonia aspiration (n/a - Unknown - Other Medically Important Condition) | OCRELIZUMAB [OCRELIZUMAB] (S - Multiple sclerosis - Drug withdrawn - [1y - n/a - Unknown]), TOZINAMERAN [TOZINAMERAN] (S - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]) |
| 178 | click or scan EU-EC-10012007845 | | 2022-03-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | [FUROSEMIDE] (S - n/a - Unknown - [n/a - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 179 | click or scan EU-EC-10012007775 | | 2022-03-24 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**), Vaccine associated enhanced disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 180 | click or scan EU-EC-10012007746 | | 2022-03-24 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 181 | click or scan EU-EC-10012007725 | | 2022-03-24 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (6d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 182 | click or scan EU-EC-10012007648 | | 2022-03-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Haemophagocytic lymphohistiocytosis (114d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Papillary cystadenoma lymphomatosum (281d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 183 | click or scan EU-EC-10012007593 | | 2022-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 184 | click or scan EU-EC-10012007376 | | 2022-03-24 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [FUROSEMIDE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 185 | click or scan EU-EC-10012006364 | | 2022-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arterial thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Carotid artery thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular insufficiency (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pupil fixed (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupillary reflex impaired (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vision blurred (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 186 | click or scan EU-EC-10012005098 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acidosis (n/a - Unknown - ), Brain stem infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral arteriosclerosis (n/a - Unknown - Other Medically Important Condition), Disseminated intravascular coagulation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic function abnormal (n/a - Unknown - ), Hyperkalaemia (n/a - Unknown - Other Medically Important Condition), Ischaemic cerebral infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Near drowning (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 187 | click or scan EU-EC-10012003382 | | 2022-03-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute left ventricular failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 188 | click or scan EU-EC-10012003312 | | 2022-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Interchange of vaccine products (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 189 | click or scan EU-EC-10012002106 | | 2022-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Encephalitis (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 190 | click or scan EU-EC-10012001942 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 191 | click or scan EU-EC-10012001708 | | 2022-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown - ), Haemorrhagic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Influenza (n/a - Unknown - ), Intestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pulmonary function test decreased (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - ), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [1d - n/a - Intramuscular]) |
| 192 | click or scan EU-EC-10012001520 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute cardiac event (n/a - Unknown - Other Medically Important Condition), Blood pressure increased (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Chronic gastritis (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dry throat (n/a - Unknown - ), Ear pain (n/a - Unknown - ), Fall (n/a - Unknown - ), Lymph node pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Musculoskeletal pain (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Toothache (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 193 | click or scan EU-EC-10012001514 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Sputum increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 194 | click or scan EU-EC-10012001489 | | 2022-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Petechiae (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Stertor (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Visceral congestion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 195 | click or scan EU-EC-10012001479 | | 2022-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysstasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Moaning (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 196 | click or scan EU-EC-10012001477 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - ), Inflammation (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 197 | click or scan EU-EC-10012001476 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Near drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 198 | click or scan EU-EC-10012001473 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 199 | click or scan EU-EC-10012001468 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 200 | click or scan EU-EC-10012001467 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 201 | click or scan EU-EC-10012001430 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 202 | click or scan EU-EC-10012001339 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 203 | click or scan EU-EC-10012000429 | | 2022-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .25mL - Intramuscular]) |
| 204 | click or scan EU-EC-10011999992 | | 2022-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abnormal loss of weight (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Lethargy (13d - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (13d - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (7d - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 205 | click or scan EU-EC-10011999992 | | 2022-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abnormal loss of weight (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Lethargy (13d - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (7d - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (13d - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (7d - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 206 | click or scan EU-EC-10011999785 | | 2022-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 207 | click or scan EU-EC-10011999575 | | 2022-03-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 208 | click or scan EU-EC-10011999165 | | 2022-03-24 | Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Not Recovered/Not Resolved - ), Hypoxia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 209 | click or scan EU-EC-10011998995 | | 2022-03-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 210 | click or scan EU-EC-10011997923 | | 2022-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 211 | click or scan EU-EC-10011997699 | | 2022-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 212 | click or scan EU-EC-10011997570 | | 2022-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular - More in ICSR]) |
| 213 | click or scan EU-EC-10011997565 | | 2022-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Depressed level of consciousness (49d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 214 | click or scan EU-EC-10011996985 | | 2022-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Carotid artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiplegia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation reaction (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 215 | click or scan EU-EC-10011996767 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphoria (n/a - Unknown - ), Hypopnoea (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 216 | click or scan EU-EC-10011996766 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 217 | click or scan EU-EC-10011996565 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Increased viscosity of bronchial secretion (n/a - Unknown - ), Mydriasis (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 218 | click or scan EU-EC-10011996503 | | 2022-03-24 | Non Healthcare Professional | EEA | Not Specified | Male | Abdominal pain upper (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Hot flush (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 219 | click or scan EU-EC-10011996497 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Social avoidant behaviour (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 220 | click or scan EU-EC-10011996497 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Social avoidant behaviour (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 221 | click or scan EU-EC-10011996305 | | 2022-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bone pain (n/a - Not Recovered/Not Resolved - ), Bundle branch block left (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cold sweat (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Duodenitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Pancreatitis acute (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral circulatory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - ), Skin discolouration (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 222 | click or scan EU-EC-10011995701 | | 2022-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Inflammatory bowel disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Intestinal obstruction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 223 | click or scan EU-EC-10011995327 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 224 | click or scan EU-EC-10011995279 | | 2022-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nasal obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 225 | click or scan EU-EC-10011995222 | | 2022-03-24 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 226 | click or scan EU-EC-10011995171 | | 2022-03-24 | Non Healthcare Professional | EEA | Not Specified | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - Other Medically Important Condition), Dementia (n/a - Unknown - Caused/Prolonged Hospitalisation), Scab (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Wound (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 227 | click or scan EU-EC-10011995108 | | 2022-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 228 | click or scan EU-EC-10011994690 | | 2022-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 229 | click or scan EU-EC-10011994608 | | 2022-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Intestinal pseudo-obstruction (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Narcolepsy (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 230 | click or scan EU-EC-10011994428 | | 2022-03-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 231 | click or scan EU-EC-10011994415 | | 2022-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 232 | click or scan EU-EC-10011994399 | | 2022-03-24 | Healthcare Professional | EEA | 18-64 Years | Female | Lymphadenopathy (53d - Fatal - **Results in Death**), Pain in extremity (53d - Fatal - **Results in Death**), Pulmonary embolism (53d - Fatal - **Results in Death**), Subclavian vein thrombosis (53d - Fatal - **Results in Death**), Swelling (53d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 233 | click or scan EU-EC-10011994398 | | 2022-03-24 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (13d - Fatal - **Results in Death**), Haemorrhage (13d - Fatal - **Results in Death**), Loss of consciousness (13d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .25mg - Intramuscular]) |
| 234 | click or scan EU-EC-10011993493 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Acute respiratory failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Bradycardia (8d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chills (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Homicide (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain in extremity (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 235 | click or scan EU-EC-10011993467 | | 2022-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 236 | click or scan EU-EC-10011993161 | | 2022-03-23 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Foetal death (1d - Fatal - **Results in Death**), Haemoperitoneum (1d - Fatal - **Results in Death**), Lymphadenitis (1d - Fatal - **Results in Death**), Pulmonary haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Transplacental]) |

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|---|---|---|---|---|---|---|---|---|---|
| 237 | click or scan EU-EC-10011993128 | | 2022-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 238 | click or scan EU-EC-10011992223 | | 2022-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 239 | click or scan EU-EC-10011992171 | | 2022-03-23 | Healthcare Professional | Non EEA | Not Specified | Male | Interchange of vaccine products (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - Unknown]) |
| 240 | click or scan EU-EC-10011992171 | | 2022-03-23 | Healthcare Professional | Non EEA | Not Specified | Male | Interchange of vaccine products (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - Unknown]) |
| 241 | click or scan EU-EC-10011991912 | | 2022-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 242 | click or scan EU-EC-10011991907 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 243 | click or scan EU-EC-10011991791 | | 2022-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 244 | click or scan EU-EC-10011991684 | | 2022-03-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular extrasystoles (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 245 | click or scan EU-EC-10011991298 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 246 | click or scan EU-EC-10011991203 | | 2022-03-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 247 | click or scan EU-EC-10011991199 | | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 248 | click or scan EU-EC-10011991195 | | 2022-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiogenic shock (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 249 | click or scan EU-EC-10011990667 | | 2022-03-23 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematoma (n/a - Not Recovered/Not Resolved - ), Monoplegia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neuralgic amyotrophy (n/a - Unknown - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vaccination site nodule (n/a - Not Recovered/Not Resolved - ), Vaccination site scar (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 250 | click or scan EU-EC-10011990606 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 251 | click or scan EU-EC-10011990592 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Toxic epidermal necrolysis (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN BENZATHINE] (S - Splenectomy - Dose not changed - [n/a - n/a - n/a]) |
| 252 | click or scan EU-EC-10011990420 | | 2022-03-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 253 | click or scan EU-EC-10011990203 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 254 | click or scan EU-EC-10011990122 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 255 | click or scan EU-EC-10011989701 |  | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Fatal - **Results in Death**), Blood glucose increased (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Hypopnoea (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 256 | click or scan EU-EC-10011989416 |  | 2022-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 257 | click or scan EU-EC-10011988916 |  | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Immune thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 258 | click or scan EU-EC-10011988916 |  | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Immune thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 259 | click or scan EU-EC-10011988914 |  | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Pancreatic carcinoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 260 | click or scan EU-EC-10011988910 |  | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 261 | click or scan EU-EC-10011988904 |  | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Brain herniation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Unknown - ), Extensor plantar response (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Headache (n/a - Unknown - ), Immune thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Language disorder (n/a - Unknown - ), Neck pain (n/a - Unknown - ), Quadriparesis (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 262 | click or scan EU-EC-10011988902 |  | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 263 | click or scan EU-EC-10011988901 |  | 2022-03-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 264 | click or scan EU-EC-10011988875 |  | 2022-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Septic shock (5d - Fatal - **Results in Death**), Thrombocytopenia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 265 | click or scan EU-EC-10011988505 | | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Female | Blood lactic acid increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cytokine release syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cytokine storm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperpyrexia (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Inflammatory marker increased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ), Necrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Petechiae (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Resuscitation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 266 | click or scan EU-EC-10011988117 | | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 267 | click or scan EU-EC-10011987934 | | 2022-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Immune thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| 268 | click or scan EU-EC-10011987929 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 269 | click or scan EU-EC-10011987750 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 270 | click or scan EU-EC-10011987696 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (0d - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 271 | click or scan EU-EC-10011987132 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastroenteritis (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .25mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 272 | click or scan EU-EC-10011987102 | | 2022-03-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 273 | click or scan EU-EC-10011986991 | | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Eosinophilic granulomatosis with polyangiitis (n/a - Fatal - **Results in Death**), Mononeuropathy multiplex (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 274 | click or scan EU-EC-10011986978 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (2d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 275 | click or scan EU-EC-10011986907 | | 2022-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 276 | click or scan EU-EC-10011986903 | | 2022-03-23 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 277 | click or scan EU-EC-10011986902 | | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 278 | click or scan EU-EC-10011986891 | | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Pneumonitis (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 279 | click or scan EU-EC-10011986550 | | 2022-03-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 280 | click or scan EU-EC-10011986504 | | 2022-03-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Vaccination complication (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 281 | click or scan EU-EC-10011985543 | | 2022-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood disorder (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fracture (n/a - Unknown - Other Medically Important Condition), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 282 | click or scan EU-EC-10011984619 | | 2022-03-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral microinfarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**), Endocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemoperitoneum (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**), Splenic rupture (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 283 | click or scan EU-EC-10011984576 | | 2022-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 284 | click or scan EU-EC-10011984575 | | 2022-03-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Angiopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Intracranial pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 285 | click or scan EU-EC-10011984521 | | 2022-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 286 | click or scan EU-EC-10011984510 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 287 | click or scan EU-EC-10011984466 | | 2022-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 288 | click or scan EU-EC-10011984464 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 289 | click or scan EU-EC-10011984436 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 290 | click or scan EU-EC-10011984343 | | 2022-03-23 | Non Healthcare Professional | EEA | Not Specified | Female | Neoplasm progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 291 | click or scan EU-EC-10011984116 | | 2022-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Vaccination complication (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 292 | click or scan EU-EC-10011984115 | | 2022-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 293 | click or scan EU-EC-10011984011 | | 2022-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 294 | click or scan EU-EC-10011983830 | | 2022-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [84d - n/a - n/a]) |
| 295 | click or scan EU-EC-10011982878 | | 2022-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 296 | click or scan EU-EC-10011982662 | | 2022-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acidosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown - ), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Listless (n/a - Recovered/Resolved - ), Oedema peripheral (n/a - Unknown - ), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary congestion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .25mL - Intramuscular - More in ICSR]) |
| 297 | click or scan EU-EC-10011982564 | | 2022-03-23 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 298 | click or scan EU-EC-10011982411 | | 2022-03-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Soft tissue necrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 299 | click or scan EU-EC-10011982265 | | 2022-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 300 | click or scan EU-EC-10011981276 | | 2022-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 301 | click or scan EU-EC-10011981238 | | 2022-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (18d - Fatal - **Results in Death**), Pyrexia (18d - Fatal - **Results in Death**), Vaccination failure (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 302 | click or scan EU-EC-10011981203 | | 2022-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Encephalitis (97d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 303 | click or scan EU-EC-10011981153 | | 2022-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myeloid leukaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 304 | click or scan EU-EC-10011980066 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 305 | click or scan EU-EC-10011980027 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 306 | click or scan EU-EC-10011979910 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 307 | click or scan EU-EC-10011979513 | | 2022-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 308 | click or scan EU-EC-10011979021 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 309 | click or scan EU-EC-10011978922 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bradycardia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 310 | click or scan EU-EC-10011978917 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blindness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Labour pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 311 | click or scan EU-EC-10011978844 | | 2022-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 312 | click or scan EU-EC-10011978620 | | 2022-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Feeling hot (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Malaise (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 313 | click or scan EU-EC-10011978610 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 314 | click or scan EU-EC-10011978602 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Interchange of vaccine products (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 315 | click or scan EU-EC-10011977072 | | 2022-03-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Acute leukaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Anaemia (n/a - Unknown - ), Back pain (n/a - Unknown - ), Coagulopathy (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Febrile neutropenia (n/a - Unknown - Other Medically Important Condition), Gingival pain (n/a - Unknown - ), Haematoma (n/a - Unknown - ), Leukocytosis (n/a - Unknown - ), Petechiae (n/a - Unknown - ), Pharyngeal erythema (n/a - Unknown - ), Platelet transfusion (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Transfusion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 316 | click or scan EU-EC-10011976307 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Akinesia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 317 | click or scan EU-EC-10011976289 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriosclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 318 | click or scan EU-EC-10011976225 | | 2022-03-22 | Non Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 319 | click or scan EU-EC-10011976100 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 320 | click or scan EU-EC-10011975406 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Embolism (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 321 | click or scan EU-EC-10011974004 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 322 | click or scan EU-EC-10011973933 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 323 | click or scan EU-EC-10011973631 | | 2022-03-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Blood creatine increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cranial nerve injury secondary to birth trauma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperpyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Necrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Petechiae (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 324 | click or scan EU-EC-10011973587 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Immunisation (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 325 | click or scan EU-EC-10011973552 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 326 | click or scan EU-EC-10011973543 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (1d - Fatal - **Results in Death**), Hyperkalaemia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hyponatraemia (n/a - Unknown - ), Listless (n/a - Unknown - ), Rhabdomyolysis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 327 | click or scan EU-EC-10011973517 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Other]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 328 | click or scan EU-EC-10011972958 | | 2022-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 329 | click or scan EU-EC-10011972783 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 330 | click or scan EU-EC-10011972761 | | 2022-03-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 331 | click or scan EU-EC-10011972496 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Leukopenia (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 332 | click or scan EU-EC-10011972489 | | 2022-03-22 | Healthcare Professional | EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 333 | click or scan EU-EC-10011972428 | | 2022-03-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arthralgia (n/a - Not Recovered/Not Resolved - ), Bacteraemia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 334 | click or scan EU-EC-10011971509 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 335 | click or scan EU-EC-10011971326 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 336 | click or scan EU-EC-10011971199 | | 2022-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 337 | click or scan EU-EC-10011971124 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal necrosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hepatic necrosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Rectal haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Visceral venous thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 338 | click or scan EU-EC-10011971087 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Male | Apraxia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ataxia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Creutzfeldt-Jakob disease (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tension headache (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Visual impairment (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 339 | click or scan EU-EC-10011971087 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Male | Apraxia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ataxia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Creutzfeldt-Jakob disease (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tension headache (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Visual impairment (74d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 340 | click or scan EU-EC-10011971042 | | 2022-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 341 | click or scan EU-EC-10011970588 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Anti-platelet factor 4 antibody positive (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cardiac hypertrophy (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 342 | click or scan EU-EC-10011970402 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anxiety (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Depression (n/a - Unknown - ), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (3mo - Unknown - ), Feeling cold (n/a - Unknown - ), Feeling of despair (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Sciatica (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 343 | click or scan EU-EC-10011970395 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bile duct stone (n/a - Unknown - Other Medically Important Condition), Cholecystitis (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 344 | click or scan EU-EC-10011970245 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Female | Autoimmune disorder (27d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Epilepsy (27d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 345 | click or scan EU-EC-10011970233 | | 2022-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 346 | click or scan EU-EC-10011969906 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 347 | click or scan EU-EC-10011969848 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 348 | click or scan EU-EC-10011969823 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 349 | click or scan EU-EC-10011969688 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Amnesia (n/a - Unknown - ), Aphasia (n/a - Unknown - ), Balance disorder (n/a - Unknown - ), Blood alkaline phosphatase decreased (n/a - Unknown - ), Blood pressure increased (n/a - Unknown - ), CSF mononuclear cell count decreased (n/a - Unknown - ), CSF polymorphonuclear cell count increased (n/a - Unknown - Other Medically Important Condition), CSF protein increased (n/a - Unknown - Other Medically Important Condition), CSF test abnormal (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - ), Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Dementia (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown - ), Irritability (n/a - Unknown - ), Mental status changes (n/a - Unknown - ), Oropharyngeal neoplasm benign (n/a - Unknown - ), Slow speech (n/a - Unknown - ), Urine abnormality (n/a - Unknown - ), Urine ketone body (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 350 | click or scan EU-EC-10011969673 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaemia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemophagocytic lymphohistiocytosis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Unknown - ), Lymphadenopathy (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Splenomegaly (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Transaminases increased (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 351 | click or scan EU-EC-10011969552 | | 2022-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 352 | click or scan EU-EC-10011969463 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 353 | click or scan EU-EC-10011968960 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 354 | click or scan EU-EC-10011968959 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 355 | click or scan EU-EC-10011968954 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 356 | click or scan EU-EC-10011968646 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 357 | click or scan EU-EC-10011968642 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 358 | click or scan EU-EC-10011968641 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 359 | click or scan EU-EC-10011968638 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 360 | click or scan EU-EC-10011968352 | | 2022-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 361 | click or scan EU-EC-10011968282 | | 2022-03-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 362 | click or scan EU-EC-10011968278 | | 2022-03-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 363 | click or scan EU-EC-10011968276 | | 2022-03-22 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), INFLUENZA A VIRUS, A/CAMBODIA/E0826360/2020 (H3N2) - LIKE STRAIN (A/TASMANIA/503/2020, IVR-221), INACTIVATED] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 364 | click or scan EU-EC-10011968273 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 365 | click or scan EU-EC-10011968272 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 366 | click or scan EU-EC-10011968271 | | 2022-03-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 367 | click or scan EU-EC-10011968262 | | 2022-03-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 368 | click or scan EU-EC-10011966574 | | 2022-03-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Internal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 369 | click or scan EU-EC-10011966544 | | 2022-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 100ug - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 370 | click or scan EU-EC-10011966419 | | 2022-03-22 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cardiac infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immune system disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 371 | click or scan EU-EC-10011966393 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 372 | click or scan EU-EC-10011966302 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Moaning (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 373 | click or scan EU-EC-10011966173 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 374 | click or scan EU-EC-10011966129 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concussion (n/a - Fatal - **Results in Death**), Neurogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Road traffic accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 375 | click or scan EU-EC-10011966126 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Metastases to liver (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Neoplasm progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 376 | click or scan EU-EC-10011966121 | | 2022-03-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 377 | click or scan EU-EC-10011966099 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 378 | click or scan EU-EC-10011966097 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 379 | click or scan EU-EC-10011965983 | | 2022-03-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Intentional product misuse (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 380 | click or scan EU-EC-10011965967 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 381 | click or scan EU-EC-10011965301 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 382 | click or scan EU-EC-10011965000 | | 2022-03-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute leukaemia (63d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Myocardial infarction (63d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 383 | click or scan EU-EC-10011964883 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Orthopnoea (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 384 | click or scan EU-EC-10011964845 | | 2022-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intradermal]) |
| 385 | click or scan EU-EC-10011964681 | | 2022-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arterial thrombosis (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 386 | click or scan EU-EC-10011964680 | | 2022-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 387 | click or scan EU-EC-10011964078 | | 2022-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 388 | click or scan EU-EC-10011963821 | | 2022-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 389 | click or scan EU-EC-10011963664 | | 2022-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac disorder (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 390 | click or scan EU-EC-10011963576 | | 2022-03-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiomegaly (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 391 | click or scan EU-EC-10011963547 | | 2022-03-22 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cardiac infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immune system disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 392 | click or scan EU-EC-10011963475 | | 2022-03-22 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Myocarditis infectious (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 393 | click or scan EU-EC-10011963320 | | 2022-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Monoplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Motor dysfunction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nail disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin ulcer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 394 | click or scan EU-EC-10011962697 | | 2022-03-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (14d - Fatal - **Results in Death**), Dysphonia (14d - Fatal - **Results in Death**), Hypotension (14d - Fatal - **Results in Death**), Pyrexia (14d - Fatal - **Results in Death**), Respiratory failure (14d - Fatal - **Results in Death**), Rhinitis (14d - Fatal - **Results in Death**), Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 395 | click or scan EU-EC-10011962016 | | 2022-03-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aortic thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jugular vein thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Venous thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 396 | click or scan EU-EC-10011961499 | | 2022-03-21 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Disorientation (n/a - Unknown - ), Hallucination (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**), Vaccine associated enhanced disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 397 | click or scan EU-EC-10011961489 | | 2022-03-21 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory alkalosis (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 398 | click or scan EU-EC-10011961477 | | 2022-03-21 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 399 | click or scan EU-EC-10011961264 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 400 | click or scan EU-EC-10011960919 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Alanine aminotransferase increased (n/a - Fatal - **Results in Death**), Blood thyroid stimulating hormone abnormal (n/a - Fatal - **Results in Death**), Brain injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Electrocardiogram QT prolonged (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 401 | click or scan EU-EC-10011960901 | | 2022-03-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Illness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 402 | click or scan EU-EC-10011960802 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 403 | click or scan EU-EC-10011960748 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 404 | click or scan EU-EC-10011960744 | | 2022-03-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 405 | click or scan EU-EC-10011960743 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 406 | click or scan EU-EC-10011960737 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 407 | click or scan EU-EC-10011960735 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 408 | click or scan EU-EC-10011960649 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 409 | click or scan EU-EC-10011960648 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 410 | click or scan EU-EC-10011960595 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Chronic disease (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 411 | click or scan EU-EC-10011960414 | | 2022-03-21 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Arthralgia (n/a - Not Recovered/Not Resolved - ), Autoimmune disorder (n/a - Unknown - Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Joint swelling (n/a - Not Recovered/Not Resolved - ), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 412 | click or scan EU-EC-10011960382 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 413 | click or scan EU-EC-10011960334 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 414 | click or scan EU-EC-10011960270 | | 2022-03-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Unknown - ), Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Feeding disorder (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyelonephritis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 415 | click or scan EU-EC-10011960121 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pulmonary oedema (1d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), [TRIHEPTANOIN] (S - Glucose transporter type 1 deficiency syndrome - Not applicable - [n/a - 200mg - Oral]) |
| 416 | click or scan EU-EC-10011959957 | | 2022-03-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 417 | click or scan EU-EC-10011959851 | | 2022-03-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 418 | click or scan EU-EC-10011959847 | | 2022-03-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 419 | click or scan EU-EC-10011959834 | | 2022-03-21 | Non Healthcare Professional | EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 420 | click or scan EU-EC-10011959832 | | 2022-03-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dizziness (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 421 | click or scan EU-EC-10011959831 | | 2022-03-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Peripheral circulatory failure (n/a - Not Recovered/Not Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 422 | click or scan EU-EC-10011959830 | | 2022-03-21 | Healthcare Professional | EEA | 65-85 Years | Male | Bickerstaff's encephalitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Miller Fisher syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 423 | click or scan EU-EC-10011959826 | | 2022-03-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 424 | click or scan EU-EC-10011959266 | | 2022-03-21 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 425 | click or scan EU-EC-10011959205 | | 2022-03-21 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 426 | click or scan EU-EC-10011959093 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 427 | click or scan EU-EC-10011958967 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Demyelination (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 428 | click or scan EU-EC-10011958424 |  | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sepsis syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 429 | click or scan EU-EC-10011958400 |  | 2022-03-21 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 430 | click or scan EU-EC-10011958046 |  | 2022-03-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood albumin decreased (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Faeces discoloured (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Unknown - Other Medically Important Condition), Haematochezia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), International normalised ratio increased (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 431 | click or scan EU-EC-10011957829 |  | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**), Overdose (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 432 | click or scan EU-EC-10011957798 |  | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse drug reaction (n/a - Fatal - **Results in Death**), Aneurysm ruptured (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 433 | click or scan EU-EC-10011957736 |  | 2022-03-21 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 434 | click or scan EU-EC-10011957701 |  | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 435 | click or scan EU-EC-10011957694 |  | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Pain in jaw (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 436 | click or scan EU-EC-10011957690 |  | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 437 | click or scan EU-EC-10011957654 | | 2022-03-21 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 438 | click or scan EU-EC-10011957640 | | 2022-03-21 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Aortic aneurysm rupture (0d - Fatal - **Results in Death**), Cardiac tamponade (0d - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Injection site inflammation (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 439 | click or scan EU-EC-10011957631 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 440 | click or scan EU-EC-10011957441 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 441 | click or scan EU-EC-10011957300 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 442 | click or scan EU-EC-10011957122 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 443 | click or scan EU-EC-10011957002 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Encephalopathy (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 444 | click or scan EU-EC-10011956742 | | 2022-03-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 445 | click or scan EU-EC-10011956719 | | 2022-03-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**), Sarcoidosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 446 | click or scan EU-EC-10011955651 | | 2022-03-21 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pneumothorax (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 447 | click or scan EU-EC-10011953094 | | 2022-03-21 | Non Healthcare Professional | EEA | More than 85 Years | Male | Purulent pericarditis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 448 | click or scan EU-EC-10011952988 | | 2022-03-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 449 | click or scan EU-EC-10011952986 | | 2022-03-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Rash (70d - Not Recovered/Not Resolved - ), Tachycardia (70d - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 450 | click or scan EU-EC-10011952970 | | 2022-03-21 | Healthcare Professional | EEA | 18-64 Years | Male | Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endocarditis (25d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic cerebral embolism (25d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Staphylococcal sepsis (25d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (13d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 451 | click or scan EU-EC-10011952309 | | 2022-03-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anxiety (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 452 | click or scan EU-EC-10011951988 | | 2022-03-21 | Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 453 | click or scan EU-EC-10011951830 | | 2022-03-21 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 454 | click or scan EU-EC-10011950613 | | 2022-03-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Apathy (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Haematuria (n/a - Unknown - ), Headache (3d - Unknown - ), Hepatic neoplasm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pancreatic carcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (3d - Unknown - ), Renal cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 455 | click or scan EU-EC-10011950579 | | 2022-03-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Discomfort (n/a - Unknown - ), Fatigue (n/a - Fatal - **Results in Death**), Ischaemic enteritis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 456 | click or scan EU-EC-10011950553 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 457 | click or scan EU-EC-10011949941 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 458 | click or scan EU-EC-10011949941 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 459 | click or scan EU-EC-10011949078 | | 2022-03-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 460 | click or scan EU-EC-10011948936 | | 2022-03-21 | Healthcare Professional | EEA | 18-64 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 461 | click or scan EU-EC-10011948901 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Neuralgia (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 462 | click or scan EU-EC-10011948894 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 463 | click or scan EU-EC-10011947964 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 464 | click or scan EU-EC-10011946907 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 465 | click or scan EU-EC-10011946879 | | 2022-03-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Foetal arrhythmia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 466 | click or scan EU-EC-10011945994 | | 2022-03-21 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Hypoxia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 467 | click or scan EU-EC-10011945919 | | 2022-03-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 468 | click or scan EU-EC-10011945775 | | 2022-03-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 469 | click or scan EU-EC-10011944835 | | 2022-03-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (70d - Fatal - **Results in Death**), Coma (70d - Fatal - **Results in Death**), Confusional state (70d - Fatal - **Results in Death**), Dysphagia (70d - Fatal - **Results in Death**), Dysphonia (70d - Fatal - **Results in Death**), Emergency care (70d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |
| 470 | click or scan EU-EC-10011944814 | | 2022-03-19 | Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**), Brain stem stroke (n/a - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Intracardiac thrombus (3d - Fatal - **Results in Death**), Myocarditis (3d - Fatal - **Results in Death**), Ventricular dysfunction (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 471 | click or scan EU-EC-10011944522 | | 2022-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 472 | click or scan EU-EC-10011939712 | | 2022-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 473 | click or scan EU-EC-10011939483 | | 2022-03-19 | Healthcare Professional | EEA | 65-85 Years | Female | Myocarditis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 474 | click or scan EU-EC-10011939428 | | 2022-03-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Intracranial aneurysm (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 475 | click or scan EU-EC-10011939316 | | 2022-03-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (5d - Fatal - **Results in Death**), Injection site reaction (5d - Fatal - **Results in Death**), Nausea (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 476 | click or scan EU-EC-10011939288 | | 2022-03-19 | Healthcare Professional | EEA | More than 85 Years | Female | Acquired haemophilia (n/a - Fatal - **Results in Death**), Anaemia (n/a - Fatal - **Results in Death**), Factor VIII deficiency (n/a - Fatal - **Results in Death**), Haematoma muscle (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 477 | click or scan EU-EC-10011937474 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 478 | click or scan EU-EC-10011937337 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 479 | click or scan EU-EC-10011937319 | | 2022-03-18 | Non Healthcare Professional | EEA | Not Specified | Female | Neck mass (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 480 | click or scan EU-EC-10011937317 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 481 | click or scan EU-EC-10011937311 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 482 | click or scan EU-EC-10011937276 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 483 | click or scan EU-EC-10011937258 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 484 | click or scan EU-EC-10011937156 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 485 | click or scan EU-EC-10011937154 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 486 | click or scan EU-EC-10011937136 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 487 | click or scan EU-EC-10011937066 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 488 | click or scan EU-EC-10011936924 |  | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Immune-mediated cholestasis (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 489 | click or scan EU-EC-10011936891 |  | 2022-03-18 | Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 immunisation (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Erysipelas (n/a - Fatal - **Results in Death**), Haemolytic anaemia (n/a - Fatal - **Results in Death**), Haemolytic uraemic syndrome (n/a - Fatal - **Results in Death**), Haemorrhagic necrotic pancreatitis (n/a - Fatal - **Results in Death**), Leg amputation (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Retroperitoneal haematoma (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 490 | click or scan EU-EC-10011936891 |  | 2022-03-18 | Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 immunisation (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Erysipelas (n/a - Fatal - **Results in Death**), Haemolytic anaemia (n/a - Fatal - **Results in Death**), Haemolytic uraemic syndrome (n/a - Fatal - **Results in Death**), Haemorrhagic necrotic pancreatitis (n/a - Fatal - **Results in Death**), Leg amputation (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Retroperitoneal haematoma (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 491 | click or scan EU-EC-10011936532 |  | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 492 | click or scan EU-EC-10011936531 |  | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 493 | click or scan EU-EC-10011936371 |  | 2022-03-18 | Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Multiple organ dysfunction syndrome (0d - Fatal - **Results in Death**), Sepsis (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 494 | click or scan EU-EC-10011936367 |  | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 495 | click or scan EU-EC-10011936210 |  | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 496 | click or scan EU-EC-10011936181 |  | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 497 | click or scan EU-EC-10011935551 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Face oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 498 | click or scan EU-EC-10011935467 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - ), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Malaise (n/a - Unknown - ), Metastasis (n/a - Unknown - Other Medically Important Condition), Muscle twitching (n/a - Unknown - ), Oedema (n/a - Unknown - ), Pain (n/a - Unknown - ), Pleural effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary mass (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 499 | click or scan EU-EC-10011935465 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 500 | click or scan EU-EC-10011935387 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 501 | click or scan EU-EC-10011935365 | | 2022-03-18 | Healthcare Professional | EEA | 18-64 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**), Cardiomegaly (0d - Fatal - **Results in Death**), Cardiovascular disorder (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Trigeminal neuralgia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 502 | click or scan EU-EC-10011935171 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 503 | click or scan EU-EC-10011935165 | | 2022-03-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 504 | click or scan EU-EC-10011935119 | | 2022-03-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 505 | click or scan EU-EC-10011935049 | | 2022-03-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (220d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema (220d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 506 | click or scan EU-EC-10011935002 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anuria (n/a - Unknown - Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 507 | click or scan EU-EC-10011934990 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic steatosis (n/a - Unknown - ), Pyrexia (0d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 508 | click or scan EU-EC-10011934983 | | 2022-03-18 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 509 | click or scan EU-EC-10011934976 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 510 | click or scan EU-EC-10011934972 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 511 | click or scan EU-EC-10011934879 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysarthria (16d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 512 | click or scan EU-EC-10011934874 | | 2022-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hiatus hernia strangulated (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 513 | click or scan EU-EC-10011934850 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agonal respiration (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 514 | click or scan EU-EC-10011934837 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 515 | click or scan EU-EC-10011934785 |  | 2022-03-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Enteritis infectious (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Medical induction of coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Prerenal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tracheostomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 516 | click or scan EU-EC-10011934783 |  | 2022-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 517 | click or scan EU-EC-10011934537 |  | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 518 | click or scan EU-EC-10011934535 |  | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 519 | click or scan EU-EC-10011934497 |  | 2022-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 520 | click or scan EU-EC-10011934271 |  | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 521 | click or scan EU-EC-10011934217 |  | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diabetic foot (n/a - Fatal - **Results in Death**), Tetanus (n/a - Fatal - **Results in Death**), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 522 | click or scan EU-EC-10011934189 |  | 2022-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | Oesophageal varices haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 523 | click or scan EU-EC-10011934098 |  | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 524 | click or scan EU-EC-10011934091 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 525 | click or scan EU-EC-10011934034 | | 2022-03-18 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**), Myeloid leukaemia (77d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 526 | click or scan EU-EC-10011933957 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 527 | click or scan EU-EC-10011933956 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 528 | click or scan EU-EC-10011933700 | | 2022-03-18 | Non Healthcare Professional | EEA | More than 85 Years | Male | SARS-CoV-2 test positive (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 529 | click or scan EU-EC-10011933669 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 530 | click or scan EU-EC-10011933465 | | 2022-03-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 531 | click or scan EU-EC-10011932946 | | 2022-03-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 532 | click or scan EU-EC-10011932879 | | 2022-03-18 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 533 | click or scan EU-EC-10011932797 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 534 | click or scan EU-EC-10011932412 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral atrophy (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 535 | click or scan EU-EC-10011932280 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mg - Intramuscular]) |
| 536 | click or scan EU-EC-10011932228 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 537 | click or scan EU-EC-10011931755 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 538 | click or scan EU-EC-10011931497 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 539 | click or scan EU-EC-10011931337 | | 2022-03-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Gastrointestinal carcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Mental disorder (n/a - Unknown - ), Neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 540 | click or scan EU-EC-10011931230 | | 2022-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Apnoea (0d - Recovered/Resolved - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Dehydration (n/a - Unknown - ), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 541 | click or scan EU-EC-10011931197 | | 2022-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 542 | click or scan EU-EC-10011931155 | | 2022-03-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (24d - Fatal - **Results in Death**, Life Threatening), Cerebrovascular accident (24d - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Enteritis infectious (24d - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (24d - Fatal - **Results in Death**, Life Threatening), Pneumonia (24d - Fatal - **Results in Death**, Life Threatening), Respiratory failure (24d - Fatal - **Results in Death**, Life Threatening), Thrombosis (24d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 543 | click or scan EU-EC-10011931085 | | 2022-03-18 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 544 | click or scan EU-EC-10011930966 | | 2022-03-18 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 545 | click or scan EU-EC-10011930833 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 546 | click or scan EU-EC-10011930134 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 547 | click or scan EU-EC-10011930000 | | 2022-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (0d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 548 | click or scan EU-EC-10011929869 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypovolaemic shock (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 549 | click or scan EU-EC-10011929767 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 550 | click or scan EU-EC-10011929404 | | 2022-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 551 | click or scan EU-EC-10011929324 | | 2022-03-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 552 | click or scan EU-EC-10011929316 | | 2022-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - .5mL - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 553 | click or scan EU-EC-10011929258 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 554 | click or scan EU-EC-10011929214 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (48h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (48h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 555 | click or scan EU-EC-10011929189 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 556 | click or scan EU-EC-10011929188 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 557 | click or scan EU-EC-10011929187 | | 2022-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 558 | click or scan EU-EC-10011929142 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 559 | click or scan EU-EC-10011928835 | | 2022-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anion gap (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bicarbonate normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood chloride normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Breath sounds abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carbon dioxide increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac telemetry (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Crepitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Differential white blood cell count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Histoplasmosis disseminated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Legionella test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell volume normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic function test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neutrophil count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 560 | click or scan EU-EC-10011928577 | | 2022-03-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 561 | click or scan EU-EC-10011928546 | | 2022-03-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral ischaemia (2d - Fatal - **Results in Death**), Hyperpyrexia (2d - Fatal - **Results in Death**), Sepsis (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 562 | click or scan EU-EC-10011926923 | | 2022-03-17 | Non Healthcare Professional | EEA | Not Specified | Female | Large intestinal obstruction (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 563 | click or scan EU-EC-10011926819 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 564 | click or scan EU-EC-10011926818 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 565 | click or scan EU-EC-10011926815 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (40d - Fatal - **Results in Death**), Drooling (39d - Fatal - **Results in Death**, Other Medically Important Condition), Gaze palsy (39d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (39d - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 566 | click or scan EU-EC-10011926749 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 567 | click or scan EU-EC-10011926644 | | 2022-03-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 568 | click or scan EU-EC-10011926639 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intrapericardial thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Jugular vein distension (n/a - Fatal - **Results in Death**), Pericardial drainage (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Suffocation feeling (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 569 | click or scan EU-EC-10011926533 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 570 | click or scan EU-EC-10011926506 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 571 | click or scan EU-EC-10011926483 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 572 | click or scan EU-EC-10011926271 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Immunisation reaction (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 573 | click or scan EU-EC-10011926252 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**), Leukaemia (n/a - Fatal - **Results in Death**), Liver injury (n/a - Fatal - **Results in Death**), Recurrent cancer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Serum ferritin increased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 574 | click or scan EU-EC-10011926116 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal discomfort (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 575 | click or scan EU-EC-10011926015 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (22d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (22d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 576 | click or scan EU-EC-10011925985 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 577 | click or scan EU-EC-10011925984 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Diastolic dysfunction (n/a - Unknown - Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), N-terminal prohormone brain natriuretic peptide increased (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Systolic dysfunction (n/a - Unknown - Other Medically Important Condition), Troponin T increased (n/a - Unknown - Other Medically Important Condition), Ventricular dysfunction (n/a - Unknown - Other Medically Important Condition), Ventricular enlargement (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 578 | click or scan EU-EC-10011925852 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bronchospasm (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 579 | click or scan EU-EC-10011925842 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 580 | click or scan EU-EC-10011925767 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Castleman's disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 581 | click or scan EU-EC-10011925664 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 582 | click or scan EU-EC-10011925614 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - ), Hepatic function abnormal (n/a - Unknown - ), Hypoglycaemia (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 583 | click or scan EU-EC-10011925005 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 584 | click or scan EU-EC-10011924846 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 585 | click or scan EU-EC-10011924829 | | 2022-03-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 586 | click or scan EU-EC-10011924747 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 587 | click or scan EU-EC-10011924198 | | 2022-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 588 | click or scan EU-EC-10011924150 | | 2022-03-17 | Healthcare Professional | EEA | 18-64 Years | Female | Acute left ventricular failure (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [BUDESONIDE, BUDESONIDE, MICRONISED] (S - Asthma - Dose not changed - [n/a - 2{DF} - Respiratory (inhalation)]), [TERBUTALINE SULFATE, TERBUTALINE SULFATE PH. EUR.] (S - Asthma - Dose not changed - [n/a - 2{DF} - Respiratory (inhalation)]) |

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|---|---|---|---|---|---|---|---|---|---|
| **589** | click or scan<br>EU-EC-10011924137 | | 2022-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Enanthema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eosinophilia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), ENTRESTO 24 MG/26 MG FILM-COATED TABLETS [VALSARTAN, SACUBITRIL] (S - Hypertension - Not applicable - [n/a - 1{DF} - Oral]), [ALLOPURINOL] (S - Hyperuricaemia - Not applicable - [n/a - 300mg - Oral]), [B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), INFLUENZA A VIRUS, A/CAMBODIA/E0826360/2020 (H3N2) - LIKE STRAIN (A/TASMANIA/503/2020, IVR-221), INACTIVATED] (S - Influenza immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [LIDOCAINE, LIDOCAINE HYDROCHLORIDE] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Cutaneous]), [SERTRALINE] (S - Depression - Not applicable - [n/a - 50mg - Oral]) |
| **590** | click or scan<br>EU-EC-10011924119 | | 2022-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiogenic shock (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 591 | click or scan EU-EC-10011924108 | | 2022-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (12d - Fatal - **Results in Death**), Vaccination failure (12d - Fatal - **Results in Death**) | CELLCEPT 500 MG TABLETS [MYCOPHENOLATE MOFETIL] (S - Antisynthetase syndrome - Drug withdrawn - [n/a - 2g - Oral]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [238d - 4 {DF} - Intramuscular]), [PREDNISONE] (S - Antisynthetase syndrome - Drug withdrawn - [n/a - 15mg - Oral]) |
| 592 | click or scan EU-EC-10011923670 | | 2022-03-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Product storage error (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 593 | click or scan EU-EC-10011923526 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 594 | click or scan EU-EC-10011923525 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 595 | click or scan EU-EC-10011923512 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ), Drug-induced liver injury (n/a - Unknown - Other Medically Important Condition), Embolism (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hepatic function abnormal (n/a - Unknown - ), Hyperuricaemia (n/a - Unknown - ), Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoproliferative disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), LEVOFLOXACIN [LEVOFLOXACIN] (S - Pneumonia - Unknown - [n/a - n/a - Oral]), [METHOTREXATE SODIUM] (S - Rheumatoid arthritis - Unknown - [n/a - n/a - Oral]) |
| 596 | click or scan EU-EC-10011923265 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (5d - Fatal - **Results in Death**), Metabolic acidosis (4d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (5d - Fatal - **Results in Death**), Oxygen saturation decreased (4d - Fatal - **Results in Death**), Peripheral swelling (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Rash maculo-papular (2d - Fatal - **Results in Death**), Septic shock (5d - Fatal - **Results in Death**), Thrombocytopenia (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 597 | click or scan EU-EC-10011923146 | | 2022-03-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiac disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Gastric disorder (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in jaw (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 598 | click or scan EU-EC-10011923000 | | 2022-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Cardiovascular disorder (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 599 | click or scan EU-EC-10011922797 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 600 | click or scan EU-EC-10011922654 | | 2022-03-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 601 | click or scan EU-EC-10011922450 | | 2022-03-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 602 | click or scan EU-EC-10011922423 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 603 | click or scan EU-EC-10011922233 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Colitis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cytomegalovirus infection reactivation (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Infection (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia pseudomonal (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Shock (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 604 | click or scan EU-EC-10011922130 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 605 | click or scan EU-EC-10011921853 | | 2022-03-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dementia Alzheimer's type (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 606 | click or scan EU-EC-10011921669 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 607 | click or scan EU-EC-10011921275 | | 2022-03-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Brain operation (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (12d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - ), Ear discomfort (n/a - Unknown - ), General anaesthesia (n/a - Unknown - ), Headache (n/a - Unknown - ), Intracranial pressure increased (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Withdrawal of life support (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]) |
| 608 | click or scan EU-EC-10011921057 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 609 | click or scan EU-EC-10011921037 | | 2022-03-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Drowning (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 610 | click or scan EU-EC-10011920978 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aspiration (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 611 | click or scan EU-EC-10011920872 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 612 | click or scan EU-EC-10011920872 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 613 | click or scan EU-EC-10011920867 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 614 | click or scan EU-EC-10011919855 | | 2022-03-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 615 | click or scan EU-EC-10011919845 | | 2022-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 616 | click or scan EU-EC-10011919766 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 617 | click or scan EU-EC-10011919086 | | 2022-03-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash macular (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 618 | click or scan EU-EC-10011919039 | | 2022-03-17 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain lower (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Ecchymosis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 619 | click or scan EU-EC-10011918999 | | 2022-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 620 | click or scan EU-EC-10011918819 | | 2022-03-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac discomfort (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 621 | click or scan EU-EC-10011918688 | | 2022-03-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intestinal ischaemia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intestinal perforation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 622 | click or scan EU-EC-10011918623 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cellulitis (n/a - Unknown - Other Medically Important Condition), Face oedema (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 623 | click or scan EU-EC-10011918601 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Unknown - ), Blood uric acid increased (n/a - Unknown - ), Condition aggravated (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hepatic function abnormal (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Presyncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 624 | click or scan EU-EC-10011918576 | | 2022-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 625 | click or scan EU-EC-10011918554 | | 2022-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | Atelectasis (n/a - Unknown - Other Medically Important Condition), Back disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - ), Cardiac failure congestive (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Depression (n/a - Unknown - ), Dysstasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hallucination (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - ), Lung consolidation (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertigo (10h - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 626 | click or scan EU-EC-10011918094 | | 2022-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Parosmia (n/a - Unknown - ), Taste disorder (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 627 | click or scan EU-EC-10011917258 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aplastic anaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased immune responsiveness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 628 | click or scan EU-EC-10011916950 | | 2022-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 629 | click or scan EU-EC-10011916880 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 630 | click or scan EU-EC-10011916829 | | 2022-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 631 | click or scan EU-EC-10011916824 | | 2022-03-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Intestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Large intestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), IRBESARTAN [IRBESARTAN] (S - n/a - Not applicable - [n/a - 1{DF} - Oral]), PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (S - n/a - Dose not changed - [n/a - 75mg - Oral]), [ACETYLSALICYLIC ACID] (S - n/a - Dose not changed - [n/a - n/a - Oral]) |
| 632 | click or scan EU-EC-10011916109 | | 2022-03-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 633 | click or scan EU-EC-10011914536 | | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bacterial sepsis (n/a - Unknown - Other Medically Important Condition), Brain injury (n/a - Unknown - Other Medically Important Condition), Breath sounds abnormal (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Discomfort (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Dysstasia (n/a - Unknown - ), Facial paresis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Monoplegia (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pupils unequal (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Reflexes abnormal (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition), Salivary hypersecretion (n/a - Unknown - Other Medically Important Condition), Slow response to stimuli (n/a - Unknown - ), Somnolence (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Visual impairment (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 634 | click or scan EU-EC-10011914241 | | 2022-03-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) |
| 635 | click or scan EU-EC-10011914014 | | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Thalamus haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (S - n/a - Unknown - [n/a - n/a - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 636 | click or scan EU-EC-10011913945 |  | 2022-03-16 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Thrombosis - Unknown - [n/a - n/a - n/a]) |
| 637 | click or scan EU-EC-10011913678 |  | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 638 | click or scan EU-EC-10011913626 |  | 2022-03-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - ), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 639 | click or scan EU-EC-10011913428 |  | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subdural haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [AMLODIPINE, AMLODIPINE BESILATE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 640 | click or scan EU-EC-10011912907 |  | 2022-03-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 641 | click or scan EU-EC-10011912769 |  | 2022-03-16 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 642 | click or scan EU-EC-10011911257 |  | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 643 | click or scan EU-EC-10011911204 |  | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 644 | click or scan EU-EC-10011911070 |  | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atrioventricular block second degree (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 645 | click or scan EU-EC-10011910919 |  | 2022-03-16 | Non Healthcare Professional | EEA | Not Specified | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Abscess (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Fatal - **Results in Death**), Hepatitis (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 646 | click or scan EU-EC-10011910710 |  | 2022-03-16 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 647 | click or scan EU-EC-10011910514 | | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 648 | click or scan EU-EC-10011909632 | | 2022-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 649 | click or scan EU-EC-10011909123 | | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Acute respiratory failure (n/a - Fatal - **Results in Death**), Areflexia (n/a - Fatal - **Results in Death**), Arteriogram carotid abnormal (n/a - Fatal - **Results in Death**), Blood culture (n/a - Fatal - **Results in Death**), Breath sounds absent (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral mass effect (n/a - Fatal - **Results in Death**), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyskinesia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Echocardiogram abnormal (n/a - Fatal - **Results in Death**), Electrocardiogram ST-T segment abnormal (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Fungal test (n/a - Fatal - **Results in Death**), Gastrointestinal sounds abnormal (n/a - Fatal - **Results in Death**), Gastrointestinal tube insertion (n/a - Fatal - **Results in Death**), Heart sounds abnormal (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**), Obesity (n/a - Fatal - **Results in Death**), Pancytopenia (n/a - Fatal - **Results in Death**), Pneumonia adenoviral (n/a - Fatal - **Results in Death**), Prone position (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Pupil fixed (n/a - Fatal - **Results in Death**), Radial pulse abnormal (n/a - Fatal - **Results in Death**), Respiratory fatigue (n/a - Fatal - **Results in Death**), Right ventricular dilatation (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Vitamin B12 deficiency (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 650 | click or scan EU-EC-10011908975 | | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperpyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 651 | click or scan EU-EC-10011908919 | | 2022-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Productive cough (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 652 | click or scan EU-EC-10011907953 | | 2022-03-16 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 653 | click or scan EU-EC-10011907483 |  | 2022-03-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 654 | click or scan EU-EC-10011907372 |  | 2022-03-16 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 655 | click or scan EU-EC-10011906692 |  | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Respiration abnormal (n/a - Unknown - ), Shock (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 656 | click or scan EU-EC-10011906664 |  | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood creatine phosphokinase increased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Palpitations (n/a - Unknown - ), Ventricular hypokinesia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 657 | click or scan EU-EC-10011906105 |  | 2022-03-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 658 | click or scan EU-EC-10011906095 |  | 2022-03-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Epilepsy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 659 | click or scan EU-EC-10011906080 |  | 2022-03-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 660 | click or scan EU-EC-10011905545 |  | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 661 | click or scan EU-EC-10011905487 |  | 2022-03-16 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 662 | click or scan EU-EC-10011905132 |  | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling cold (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 663 | click or scan EU-EC-10011904750 | | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypotension (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 664 | click or scan EU-EC-10011904678 | | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intermenstrual bleeding (n/a - Recovering/Resolving - ), Orthopnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 665 | click or scan EU-EC-10011904678 | | 2022-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intermenstrual bleeding (n/a - Recovering/Resolving - ), Orthopnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 666 | click or scan EU-EC-10011904505 | | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 667 | click or scan EU-EC-10011904486 | | 2022-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 668 | click or scan EU-EC-10011904049 | | 2022-03-16 | Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 669 | click or scan EU-EC-10011904021 | | 2022-03-16 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .25mL - Intramuscular]) |
| 670 | click or scan EU-EC-10011903979 | | 2022-03-16 | Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 671 | click or scan EU-EC-10011900096 | | 2022-03-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Disseminated intravascular coagulation (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 672 | click or scan EU-EC-10011899240 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 673 | click or scan EU-EC-10011898065 | | 2022-03-15 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Unknown - ), Cyanosis (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ecchymosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Generalised oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Injection site reaction (n/a - Unknown - ), Lymph node pain (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Platelet count decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 674 | click or scan EU-EC-10011897764 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Respiratory distress (n/a - Unknown - ), Sudden infant death syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 675 | click or scan EU-EC-10011897757 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 676 | click or scan EU-EC-10011897577 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 677 | click or scan EU-EC-10011897415 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Near drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 678 | click or scan EU-EC-10011897157 | | 2022-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (15d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 679 | click or scan EU-EC-10011897045 | | 2022-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 680 | click or scan EU-EC-10011896997 | | 2022-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Haemorrhage (n/a - Fatal - **Results in Death**, Disabling), Lethargy (14d - Fatal - **Results in Death**, Disabling), Loss of consciousness (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |
| 681 | click or scan EU-EC-10011896208 | | 2022-03-15 | Healthcare Professional | EEA | Not Specified | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Livedo reticularis (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 682 | click or scan EU-EC-10011896114 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood creatine phosphokinase MB increased (n/a - Unknown - ), Blood creatine phosphokinase increased (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Ejection fraction decreased (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Haemoptysis (n/a - Unknown - ), Headache (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition), Myocardial oedema (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Peripheral coldness (n/a - Unknown - ), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Rales (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rib fracture (n/a - Fatal - **Results in Death**), Staphylococcal infection (n/a - Unknown - ), Troponin I increased (n/a - Unknown - ), Viral myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 683 | click or scan EU-EC-10011896110 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (3885min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 684 | click or scan EU-EC-10011896100 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 685 | click or scan EU-EC-10011896096 | | 2022-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 686 | click or scan EU-EC-10011896064 | | 2022-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 687 | click or scan EU-EC-10011896062 | | 2022-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Hypoxia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 688 | click or scan EU-EC-10011895965 | | 2022-03-15 | Healthcare Professional | EEA | 18-64 Years | Male | Rhabdomyolysis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 689 | click or scan EU-EC-10011895949 | | 2022-03-15 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 690 | click or scan EU-EC-10011895882 | | 2022-03-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [212d - 1{DF} - Intramuscular]) |
| 691 | click or scan EU-EC-10011895880 | | 2022-03-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 692 | click or scan EU-EC-10011895877 | | 2022-03-15 | Healthcare Professional | EEA | Not Specified | Male | Congenital tricuspid valve atresia (n/a - Fatal - **Results in Death**, Congenital Anomaly), Ventricular septal defect (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1{DF} - Transplacental]) |
| 693 | click or scan EU-EC-10011895622 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Ventricular dysfunction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 694 | click or scan EU-EC-10011895137 | | 2022-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 695 | click or scan EU-EC-10011895099 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling hot (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 696 | click or scan EU-EC-10011895052 | | 2022-03-15 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 697 | click or scan EU-EC-10011894930 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 698 | click or scan EU-EC-10011894791 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 699 | click or scan EU-EC-10011894780 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pemphigoid (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **700** | click or scan EU-EC-10011894506 | | 2022-03-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pain in extremity (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **701** | click or scan EU-EC-10011894505 | | 2022-03-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **702** | click or scan EU-EC-10011894497 | | 2022-03-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Granulomatosis with polyangiitis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **703** | click or scan<br><br>EU-EC-10011893737 | | 2022-03-15 | Healthcare Professional | EEA | 18-64 Years | Male | General physical health deterioration (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoglycaemia (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]), [ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FIMBRIAE TYPE 2 AND 3 ADSORBED ON ALUMINIUM PHOSPHATE, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, POLIOVIRUS TYPE 1 (INACTIVATED), POLIOVIRUS TYPE 2 (INACTIVATED), POLIOVIRUS TYPE 3 (INACTIVATED), PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 1 PRODUCED IN VERO CELLS, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 2 PRODUCED IN VERO CELLS, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 3 PRODUCED IN VERO CELLS, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS, POLIOVIRUS TYPE 1, POLIOVIRUS TYPE 2, POLIOVIRUS TYPE 3] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 704 | click or scan EU-EC-10011893685 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia viral (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Viral test positive (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 705 | click or scan EU-EC-10011893680 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 706 | click or scan EU-EC-10011893100 | | 2022-03-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - ), Illness (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 707 | click or scan EU-EC-10011893091 | | 2022-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pancreatic carcinoma (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 708 | click or scan EU-EC-10011892706 | | 2022-03-15 | Healthcare Professional | EEA | 18-64 Years | Female | Balance disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cognitive disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed mood (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Personality change (331d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 709 | click or scan EU-EC-10011892394 | | 2022-03-15 | Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (3d - Fatal - **Results in Death**), Cerebral haemorrhage (3d - Fatal - **Results in Death**), Cerebral mass effect (3d - Fatal - **Results in Death**), Coagulopathy (3d - Fatal - **Results in Death**), Unresponsive to stimuli (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 710 | click or scan EU-EC-10011892343 | | 2022-03-15 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 711 | click or scan EU-EC-10011892244 | | 2022-03-15 | Healthcare Professional | EEA | 65-85 Years | Male | Capillary leak syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoalbuminaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 712 | click or scan EU-EC-10011890362 | | 2022-03-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 713 | click or scan EU-EC-10011890358 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Unknown - ), Upper respiratory tract infection (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 714 | click or scan EU-EC-10011890340 | | 2022-03-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 715 | click or scan EU-EC-10011890335 | | 2022-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiomegaly (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 716 | click or scan EU-EC-10011890270 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Interstitial lung disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 717 | click or scan EU-EC-10011890239 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Subdural haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 718 | click or scan EU-EC-10011890219 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaphylactic reaction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Flushing (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 719 | click or scan EU-EC-10011890137 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 720 | click or scan EU-EC-10011890083 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Syncope (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 721 | click or scan EU-EC-10011890075 | | 2022-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 722 | click or scan EU-EC-10011889840 | | 2022-03-15 | Healthcare Professional | EEA | 18-64 Years | Male | Hepatocellular carcinoma (28d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 723 | click or scan EU-EC-10011889133 | | 2022-03-15 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 724 | click or scan EU-EC-10011888965 | | 2022-03-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Body temperature increased (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Monoplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 725 | click or scan EU-EC-10011888880 | | 2022-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 726 | click or scan EU-EC-10011888774 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 727 | click or scan EU-EC-10011888597 | | 2022-03-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 728 | click or scan EU-EC-10011887767 | | 2022-03-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 729 | click or scan EU-EC-10011887740 | | 2022-03-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 730 | click or scan EU-EC-10011887721 | | 2022-03-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Heart rate abnormal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 731 | click or scan EU-EC-10011887698 | | 2022-03-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Burning sensation (n/a - Fatal - **Results in Death**), Cystitis haemorrhagic (n/a - Fatal - **Results in Death**), Dysentery (n/a - Fatal - **Results in Death**), Hepatic neoplasm (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 732 | click or scan EU-EC-10011887678 | | 2022-03-15 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (3d - Fatal - **Results in Death**), Back pain (3d - Fatal - **Results in Death**), Fatigue (3d - Fatal - **Results in Death**), Gastric haemorrhage (3d - Fatal - **Results in Death**), Pallor (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Vaccination site pain (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 733 | click or scan EU-EC-10011887645 | | 2022-03-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Chillblains (n/a - Fatal - **Results in Death**), Psoriatic arthropathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 734 | click or scan EU-EC-10011887564 | | 2022-03-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |
| 735 | click or scan EU-EC-10011887537 | | 2022-03-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 736 | click or scan EU-EC-10011886830 | | 2022-03-14 | Healthcare Professional | Non EEA | Not Specified | Female | Anal incontinence (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Aphasia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Asphyxia (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Dementia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Epilepsy (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Mobility decreased (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 737 | click or scan EU-EC-10011886007 | | 2022-03-14 | Healthcare Professional | EEA | More than 85 Years | Male | Radiculopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 738 | click or scan EU-EC-10011885652 | | 2022-03-14 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 739 | click or scan EU-EC-10011885278 | | 2022-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 740 | click or scan EU-EC-10011885217 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 741 | click or scan EU-EC-10011885210 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 742 | click or scan EU-EC-10011884872 | | 2022-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Angina pectoris (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **743** | click or scan EU-EC-10011884731 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **744** | click or scan EU-EC-10011884731 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **745** | click or scan EU-EC-10011884495 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **746** | click or scan EU-EC-10011884419 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **747** | click or scan EU-EC-10011884414 | | 2022-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cognitive disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [0y - n/a - Intramuscular]) |
| **748** | click or scan EU-EC-10011884406 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myeloid leukaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diffuse large B-cell lymphoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epstein-Barr virus infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic function abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic mass (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypogammaglobulinaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Jaundice cholestatic (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Monocyte count abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Myelodysplastic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Red blood cell morphology abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell morphology abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 749 | click or scan EU-EC-10011884387 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood creatine phosphokinase MB increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac dysfunction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Echocardiogram (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram ST segment depression (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Liver injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphocytic infiltration (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 750 | click or scan EU-EC-10011884096 | | 2022-03-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Anaemia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cardiac disorder (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**), Fungaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 751 | click or scan EU-EC-10011884057 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 752 | click or scan EU-EC-10011884056 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 753 | click or scan EU-EC-10011883776 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 754 | click or scan EU-EC-10011883769 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 755 | click or scan EU-EC-10011883584 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden cardiac death (1wk - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 756 | click or scan EU-EC-10011882869 | | 2022-03-14 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [29d - 1mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 757 | click or scan EU-EC-10011882866 | | 2022-03-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic aneurysm rupture (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 758 | click or scan EU-EC-10011882840 | | 2022-03-14 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (34d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 759 | click or scan EU-EC-10011882747 | | 2022-03-14 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [76d - 2 {DF} - Intramuscular]) |
| 760 | click or scan EU-EC-10011882741 | | 2022-03-14 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [242d - 3 {DF} - Intramuscular]) |
| 761 | click or scan EU-EC-10011882588 | | 2022-03-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Influenza (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 762 | click or scan EU-EC-10011882122 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Erythema (n/a - Unknown - ), Hepatic steatosis (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Liver disorder (n/a - Unknown - ), Obesity (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Unknown - ), Troponin increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 763 | click or scan EU-EC-10011882076 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Other Medically Important Condition), Intestinal ischaemia (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - ), Peritonitis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vascular device infection (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 764 | click or scan EU-EC-10011882042 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Breath sounds abnormal (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 765 | click or scan EU-EC-10011882034 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic active Epstein-Barr virus infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 766 | click or scan EU-EC-10011882023 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 767 | click or scan EU-EC-10011881818 | | 2022-03-14 | Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Meningoencephalitis herpetic (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nervous system disorder (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 768 | click or scan EU-EC-10011880228 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Body temperature (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neutropenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neutropenic sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen consumption increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 769 | click or scan EU-EC-10011880167 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 770 | click or scan EU-EC-10011879867 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition), Oedema peripheral (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 771 | click or scan EU-EC-10011879814 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 772 | click or scan EU-EC-10011879242 | | 2022-03-14 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) |
| 773 | click or scan EU-EC-10011879225 | | 2022-03-14 | Healthcare Professional | EEA | 18-64 Years | Male | Brain injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 774 | click or scan EU-EC-10011879207 | | 2022-03-14 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 775 | click or scan EU-EC-10011879013 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 776 | click or scan EU-EC-10011878943 | | 2022-03-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 777 | click or scan EU-EC-10011878786 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 778 | click or scan EU-EC-10011878782 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 779 | click or scan EU-EC-10011878438 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening), Back pain (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 780 | click or scan EU-EC-10011878147 | | 2022-03-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 781 | click or scan EU-EC-10011878131 | | 2022-03-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 782 | click or scan EU-EC-10011878120 | | 2022-03-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pneumothorax (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 783 | click or scan EU-EC-10011877609 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 784 | click or scan EU-EC-10011877556 | | 2022-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 785 | click or scan EU-EC-10011877535 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 786 | click or scan EU-EC-10011877501 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 787 | click or scan EU-EC-10011877457 | | 2022-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 788 | click or scan EU-EC-10011877446 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 789 | click or scan EU-EC-10011877373 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain oedema (n/a - Unknown - Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematoma muscle (n/a - Unknown - ), Peptostreptococcus infection (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**), Shock (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 790 | click or scan EU-EC-10011875938 | | 2022-03-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 791 | click or scan EU-EC-10011875895 | | 2022-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 792 | click or scan EU-EC-10011875596 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 793 | click or scan EU-EC-10011875203 | | 2022-03-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Intestinal infarction (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Venous thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 794 | click or scan EU-EC-10011873058 | | 2022-03-12 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 795 | click or scan EU-EC-10011873022 | | 2022-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 796 | click or scan EU-EC-10011872949 | | 2022-03-12 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 797 | click or scan EU-EC-10011872941 | | 2022-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 798 | click or scan EU-EC-10011871359 | | 2022-03-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 799 | click or scan EU-EC-10011871171 | | 2022-03-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 800 | click or scan EU-EC-10011870973 | | 2022-03-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 801 | click or scan EU-EC-10011869552 | | 2022-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Obstructive airways disorder (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 802 | click or scan EU-EC-10011869549 | | 2022-03-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 803 | click or scan EU-EC-10011869548 | | 2022-03-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Unknown - ), Malaise (n/a - Unknown - ), Odynophagia (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 804 | click or scan EU-EC-10011869300 | | 2022-03-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 805 | click or scan EU-EC-10011869096 | | 2022-03-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Hepatic pain (n/a - Fatal - **Results in Death**), Taste disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 806 | click or scan EU-EC-10011868958 | | 2022-03-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5 {DF} - Intramuscular]) |
| 807 | click or scan EU-EC-10011868784 | | 2022-03-12 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (24d - Fatal - **Results in Death**), Acute respiratory failure (24d - Fatal - **Results in Death**), COVID-19 pneumonia (24d - Fatal - **Results in Death**), Pneumonia (24d - Fatal - **Results in Death**), Pulmonary embolism (24d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 808 | click or scan EU-EC-10011868672 | | 2022-03-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Ruptured cerebral aneurysm (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 809 | click or scan EU-EC-10011868668 | | 2022-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 810 | click or scan EU-EC-10011868379 | | 2022-03-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Leukaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 811 | click or scan EU-EC-10011866495 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 812 | click or scan EU-EC-10011866493 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 813 | click or scan EU-EC-10011866021 | | 2022-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Balance disorder (n/a - Unknown - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Unknown - **Results in Death**), Dysarthria (n/a - Unknown - **Results in Death**), Gait disturbance (n/a - Unknown - **Results in Death**), Motor dysfunction (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 814 | click or scan EU-EC-10011865821 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 815 | click or scan EU-EC-10011865792 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 816 | click or scan EU-EC-10011865792 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 817 | click or scan EU-EC-10011865779 |  | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 818 | click or scan EU-EC-10011865775 |  | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 819 | click or scan EU-EC-10011865530 |  | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 820 | click or scan EU-EC-10011865477 |  | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Ocular icterus (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 821 | click or scan EU-EC-10011865469 |  | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 822 | click or scan EU-EC-10011865173 |  | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 823 | click or scan EU-EC-10011865099 |  | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Peripheral artery occlusion (n/a - Fatal - **Results in Death**, Disabling) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 824 | click or scan EU-EC-10011865037 |  | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 825 | click or scan EU-EC-10011865025 |  | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Odynophagia (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 826 | click or scan EU-EC-10011864898 |  | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 827 | click or scan EU-EC-10011864794 | | 2022-03-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (1d - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 828 | click or scan EU-EC-10011864758 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 829 | click or scan EU-EC-10011864754 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 830 | click or scan EU-EC-10011864744 | | 2022-03-11 | Healthcare Professional | EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Not Recovered/Not Resolved - Life Threatening), Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 831 | click or scan EU-EC-10011864542 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - ), Body temperature increased (n/a - Unknown - ), Bronchospasm (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Diffuse alveolar damage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation), Eye pain (n/a - Unknown - ), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown - ), Hilar lymphadenopathy (n/a - Unknown - ), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - ), Lymphadenopathy mediastinal (n/a - Unknown - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Ocular hyperaemia (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - ), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sensitive skin (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 832 | click or scan EU-EC-10011864530 | | 2022-03-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Hemiplegia (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 833 | click or scan EU-EC-10011864512 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 834 | click or scan EU-EC-10011864496 | | 2022-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 835 | click or scan EU-EC-10011864205 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (92d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 836 | click or scan EU-EC-10011863983 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 837 | click or scan EU-EC-10011863841 | | 2022-03-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 838 | click or scan EU-EC-10011863365 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), SARS-CoV-2 carrier (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 839 | click or scan EU-EC-10011862844 | | 2022-03-11 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 840 | click or scan EU-EC-10011862711 | | 2022-03-11 | Healthcare Professional | EEA | 18-64 Years | Female | Carotid artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 841 | click or scan EU-EC-10011862646 | | 2022-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [202d - 1 {DF} - Intramuscular]) |
| 842 | click or scan EU-EC-10011862630 | | 2022-03-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Lymphoma (n/a - Fatal - **Results in Death**), Unmasking of previously unidentified disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 843 | click or scan EU-EC-10011862604 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Immobile (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 844 | click or scan EU-EC-10011862376 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 845 | click or scan EU-EC-10011862369 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dehydration (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 846 | click or scan EU-EC-10011862354 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Insomnia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 847 | click or scan EU-EC-10011862353 | | 2022-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Colon cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 848 | click or scan EU-EC-10011862350 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 849 | click or scan EU-EC-10011861999 | | 2022-03-11 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 850 | click or scan EU-EC-10011861955 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 851 | click or scan EU-EC-10011861955 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 852 | click or scan EU-EC-10011861890 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 853 | click or scan EU-EC-10011861859 | | 2022-03-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**), Hypoglycaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 854 | click or scan EU-EC-10011861838 | | 2022-03-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 855 | click or scan EU-EC-10011861825 | | 2022-03-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 856 | click or scan EU-EC-10011861699 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 857 | click or scan EU-EC-10011861695 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Foetal death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 858 | click or scan EU-EC-10011861085 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 859 | click or scan EU-EC-10011860955 | | 2022-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (89d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 860 | click or scan EU-EC-10011860932 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 861 | click or scan EU-EC-10011860926 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 862 | click or scan EU-EC-10011860904 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 863 | click or scan EU-EC-10011860700 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Ear pruritus (n/a - Unknown - ), Fluid retention (n/a - Unknown - ), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Mucosal haemorrhage (n/a - Unknown - ), Petechiae (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (n/a - Recovering/Resolving - ), Purpura (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Rash (n/a - Recovered/Resolved - ), Thrombocytopenic purpura (n/a - Unknown - Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 864 | click or scan EU-EC-10011860334 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 865 | click or scan EU-EC-10011860331 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 866 | click or scan EU-EC-10011860182 | | 2022-03-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed mood (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Oral]) |
| 867 | click or scan EU-EC-10011860060 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 868 | click or scan EU-EC-10011859944 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 869 | click or scan EU-EC-10011859865 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain contusion (5min - Fatal - **Results in Death**), COVID-19 (5min - Fatal - **Results in Death**), Dyspnoea (5min - Fatal - **Results in Death**), End stage renal disease (5min - Fatal - **Results in Death**), Nephrosclerosis (5min - Fatal - **Results in Death**), Pneumonia (5min - Fatal - **Results in Death**), Uraemic encephalopathy (5min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 870 | click or scan EU-EC-10011859864 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 871 | click or scan EU-EC-10011859123 | | 2022-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drowning (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .25mL - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 872 | click or scan EU-EC-10011858254 | | 2022-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**), COVID-19 immunisation (2d - Fatal - **Results in Death**), Cardiovascular disorder (2d - Fatal - **Results in Death**), Chest discomfort (2d - Fatal - **Results in Death**), Chills (2d - Fatal - **Results in Death**), Coronary artery occlusion (2d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Influenza like illness (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Respiratory disorder (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 873 | click or scan EU-EC-10011858187 | | 2022-03-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - n/a]) |
| 874 | click or scan EU-EC-10011858059 | | 2022-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 875 | click or scan EU-EC-10011857736 | | 2022-03-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 876 | click or scan EU-EC-10011857697 | | 2022-03-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 877 | click or scan EU-EC-10011857444 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Splenomegaly (n/a - Unknown - ), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 878 | click or scan EU-EC-10011857318 | | 2022-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 879 | click or scan EU-EC-10011857230 | | 2022-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 880 | click or scan EU-EC-10011857191 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 881 | click or scan EU-EC-10011857072 | | 2022-03-11 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fall (n/a - Not Recovered/Not Resolved - ), Hypersomnia (n/a - Not Recovered/Not Resolved - ), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Muscular weakness (n/a - Not Recovered/Not Resolved - ), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - ), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 882 | click or scan EU-EC-10011857064 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 883 | click or scan EU-EC-10011857061 | | 2022-03-11 | Healthcare Professional | EEA | 18-64 Years | Female | Malaise (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 884 | click or scan EU-EC-10011857056 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 885 | click or scan EU-EC-10011857053 | | 2022-03-11 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - ), Infection (n/a - Unknown - ), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 886 | click or scan EU-EC-10011857045 | | 2022-03-11 | Healthcare Professional | Non EEA | Not Specified | Male | Seizure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 887 | click or scan EU-EC-10011857031 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 888 | click or scan EU-EC-10011856818 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 889 | click or scan EU-EC-10011856797 | | 2022-03-11 | Healthcare Professional | Non EEA | Not Specified | Male | Cold sweat (n/a - Fatal - **Results in Death**), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 890 | click or scan EU-EC-10011856795 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adjustment disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Animal bite (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Systemic viral infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 891 | click or scan EU-EC-10011856790 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 892 | click or scan EU-EC-10011856758 | | 2022-03-11 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 893 | click or scan EU-EC-10011856717 | | 2022-03-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Immune system disorder (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - ), Neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Pancreatitis (n/a - Unknown - Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 894 | click or scan EU-EC-10011856715 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 895 | click or scan EU-EC-10011856447 | | 2022-03-11 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 896 | click or scan EU-EC-10011856236 | | 2022-03-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 897 | click or scan EU-EC-10011856084 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 898 | click or scan EU-EC-10011856066 | | 2022-03-11 | Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Brain oedema (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Haematoma (n/a - Unknown - ), Hypokinesia (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Skin abrasion (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 899 | click or scan EU-EC-10011856065 | | 2022-03-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 900 | click or scan EU-EC-10011856012 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 901 | click or scan EU-EC-10011855895 | | 2022-03-11 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 902 | click or scan EU-EC-10011855474 | | 2022-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 903 | click or scan EU-EC-10011855283 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bradycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 904 | click or scan EU-EC-10011855227 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 905 | click or scan EU-EC-10011855193 | | 2022-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 906 | click or scan EU-EC-10011855185 | | 2022-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 907 | click or scan EU-EC-10011853875 | | 2022-03-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Confusional state (n/a - Recovered/Resolved - Other Medically Important Condition), Respiratory depression (n/a - Fatal - **Results in Death**), Sedation (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]), [ALIMEMAZINE TARTRATE, AMMONIUM ACETATE, EPHEDRINE HYDROCHLORIDE, ETHYLMORPHINE HYDROCHLORIDE] (I - Anxiolytic therapy - Drug withdrawn - [7d - 40mg - Oral]), [CYAMEMAZINE, CYAMEMAZINE TARTRATE] (I - Withdrawal syndrome - Drug withdrawn - [5d - 150mg - Oral]), [DIAZEPAM] (I - Withdrawal syndrome - Dose reduced - [7d - 40mg - Oral]), [METHADONE HYDROCHLORIDE] (I - Withdrawal syndrome - Dose not changed - [6d - 2 {DF} - Oral]) |
| 908 | click or scan EU-EC-10011853508 | | 2022-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 909 | click or scan EU-EC-10011853475 | | 2022-03-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **910** | click or scan EU-EC-10011853215 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Peripheral circulatory failure (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **911** | click or scan EU-EC-10011853118 | | 2022-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **912** | click or scan EU-EC-10011852642 | | 2022-03-10 | Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Epistaxis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **913** | click or scan EU-EC-10011852459 | | 2022-03-10 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Stress cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **914** | click or scan EU-EC-10011852260 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **915** | click or scan EU-EC-10011851847 | | 2022-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **916** | click or scan EU-EC-10011850178 | | 2022-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Acquired haemophilia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **917** | click or scan EU-EC-10011849642 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Carotid artery occlusion (n/a - Unknown - Other Medically Important Condition), Cerebral artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Embolic stroke (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Unknown - ), Strabismus (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **918** | click or scan EU-EC-10011849361 | | 2022-03-10 | Healthcare Professional | Non EEA | Not Specified | Male | Foetal death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **919** | click or scan EU-EC-10011849293 | | 2022-03-10 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 920 | click or scan EU-EC-10011848886 | | 2022-03-10 | Healthcare Professional | EEA | 65-85 Years | Female | Ascites (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastritis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lymphoedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peritonitis bacterial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 921 | click or scan EU-EC-10011848523 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 922 | click or scan EU-EC-10011846847 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 923 | click or scan EU-EC-10011846632 | | 2022-03-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 924 | click or scan EU-EC-10011846617 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 925 | click or scan EU-EC-10011846290 | | 2022-03-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (50d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oedema peripheral (50d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 926 | click or scan EU-EC-10011846185 | | 2022-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 927 | click or scan EU-EC-10011845745 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 928 | click or scan EU-EC-10011845472 | | 2022-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 929 | click or scan EU-EC-10011844888 | | 2022-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 930 | click or scan EU-EC-10011844759 | | 2022-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 931 | click or scan EU-EC-10011844081 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 932 | click or scan EU-EC-10011843648 | | 2022-03-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Malaise (1d - Recovered/Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 933 | click or scan EU-EC-10011843403 | | 2022-03-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 934 | click or scan EU-EC-10011843279 | | 2022-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Capillary leak syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 935 | click or scan EU-EC-10011843107 | | 2022-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Akinesia (n/a - Unknown - Other Medically Important Condition), Apnoea (n/a - Unknown - Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Muscle spasms (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 936 | click or scan EU-EC-10011843061 | | 2022-03-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 937 | click or scan EU-EC-10011842034 | | 2022-03-10 | Non Healthcare Professional | EEA | Not Specified | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 938 | click or scan EU-EC-10011841863 | | 2022-03-10 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 939 | click or scan EU-EC-10011841277 | | 2022-03-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Catarrh (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Nausea (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 940 | click or scan EU-EC-10011841274 | | 2022-03-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 941 | click or scan EU-EC-10011841245 | | 2022-03-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Bronchitis chronic (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 942 | click or scan EU-EC-10011841094 | | 2022-03-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Generalised oedema (n/a - Fatal - **Results in Death**), Gravitational oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 943 | click or scan EU-EC-10011840961 | | 2022-03-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (0d - Fatal - **Results in Death**), Blood pressure increased (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Chest pain (0d - Fatal - **Results in Death**), Pallor (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 944 | click or scan EU-EC-10011839229 | | 2022-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 945 | click or scan EU-EC-10011838825 | | 2022-03-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous sinus thrombosis (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 946 | click or scan EU-EC-10011838601 | | 2022-03-09 | Healthcare Professional | Non EEA | Not Specified | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 947 | click or scan EU-EC-10011838583 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 948 | click or scan EU-EC-10011838249 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 949 | click or scan EU-EC-10011838151 | | 2022-03-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 950 | click or scan EU-EC-10011838080 | | 2022-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 951 | click or scan EU-EC-10011837878 | | 2022-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gaze palsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Incontinence (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Syncope (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 952 | click or scan EU-EC-10011837711 | | 2022-03-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), Chills (n/a - Unknown - ), Cough (n/a - Fatal - **Results in Death**, Life Threatening), Insomnia (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Nasopharyngitis (n/a - Fatal - **Results in Death**, Life Threatening), Nausea (n/a - Unknown - ), Peripheral coldness (n/a - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 953 | click or scan EU-EC-10011837319 | | 2022-03-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 954 | click or scan EU-EC-10011837314 | | 2022-03-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 955 | click or scan EU-EC-10011837180 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 956 | click or scan EU-EC-10011836750 | | 2022-03-09 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemianopia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 957 | click or scan EU-EC-10011836567 | | 2022-03-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Tremor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **958** | click or scan EU-EC-10011836521 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [98d - 3{DF} - Intramuscular]) |
| **959** | click or scan EU-EC-10011836521 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [98d - 3{DF} - Intramuscular]) |
| **960** | click or scan EU-EC-10011835870 | | 2022-03-09 | Non Healthcare Professional | EEA | Not Specified | Male | Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **961** | click or scan EU-EC-10011835625 | | 2022-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Diabetes mellitus (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **962** | click or scan EU-EC-10011835447 | | 2022-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cellulitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **963** | click or scan EU-EC-10011835390 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cachexia (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **964** | click or scan EU-EC-10011835132 | | 2022-03-09 | Healthcare Professional | EEA | 18-64 Years | Female | Arteritis coronary (n/a - Fatal - **Results in Death**), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **965** | click or scan EU-EC-10011835071 | | 2022-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **966** | click or scan EU-EC-10011834921 | | 2022-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anti-neutrophil cytoplasmic antibody positive vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Glomerulonephritis rapidly progressive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**), Mass (n/a - Unknown - ), Nephritis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 967 | click or scan EU-EC-10011834915 | | 2022-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrioventricular block complete (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac dysfunction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Conduction disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Congestive hepatopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Left ventricular dysfunction (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multi-organ disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary congestion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Small intestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin T increased (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 968 | click or scan EU-EC-10011834847 | | 2022-03-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 969 | click or scan EU-EC-10011834789 | | 2022-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - .05mL - Intramuscular]) |
| 970 | click or scan EU-EC-10011834473 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | Dehydration (131d - Fatal - **Results in Death**), Demyelinating polyneuropathy (131d - Fatal - **Results in Death**), General physical health deterioration (131d - Fatal - **Results in Death**), Leukoencephalopathy (131d - Fatal - **Results in Death**), Liver function test abnormal (131d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 971 | click or scan EU-EC-10011834251 | | 2022-03-09 | Healthcare Professional | EEA | 18-64 Years | Male | Haemorrhage (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Unknown]) |
| 972 | click or scan EU-EC-10011833898 | | 2022-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 973 | click or scan EU-EC-10011833366 | | 2022-03-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (106d - Fatal - **Results in Death**), Dysphonia (208d - Fatal - **Results in Death**), Muscle atrophy (139d - Fatal - **Results in Death**), Oropharyngeal discomfort (194d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 974 | click or scan EU-EC-10011832316 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 975 | click or scan EU-EC-10011832255 | | 2022-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 976 | click or scan EU-EC-10011831650 | | 2022-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 977 | click or scan EU-EC-10011831439 | | 2022-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Epilepsy (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Tetany (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 978 | click or scan EU-EC-10011831137 | | 2022-03-09 | Healthcare Professional | EEA | 18-64 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Brain stem infarction (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Embolic cerebral infarction (n/a - Fatal - **Results in Death**), Tachycardia induced cardiomyopathy (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [170d - n/a - Intramuscular]) |
| 979 | click or scan EU-EC-10011830781 | | 2022-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Dysstasia (n/a - Unknown - Other Medically Important Condition), Eosinophilic myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Haematuria (n/a - Unknown - Other Medically Important Condition), Hepatocellular injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyponatraemia (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pollakiuria (n/a - Unknown - Other Medically Important Condition), Pulmonary mass (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Splenomegaly (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thymoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 980 | click or scan EU-EC-10011830099 | | 2022-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse drug reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Adverse drug reaction - Not applicable - [n/a - n/a - Intramuscular]) |
| 981 | click or scan EU-EC-10011829947 | | 2022-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) |
| 982 | click or scan EU-EC-10011829585 | | 2022-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac tamponade (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 983 | click or scan EU-EC-10011829240 | | 2022-03-09 | Healthcare Professional | Non EEA | Not Specified | Male | Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 984 | click or scan EU-EC-10011828803 | | 2022-03-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ecchymosis (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 985 | click or scan EU-EC-10011828799 | | 2022-03-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 986 | click or scan EU-EC-10011828715 | | 2022-03-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 987 | click or scan EU-EC-10011828203 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Activated partial thromboplastin time shortened (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Antibody test positive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood fibrinogen decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood lactate dehydrogenase normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Craniotomy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemoglobin normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemostasis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haptoglobin normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immunoglobulin therapy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neurological decompensation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ovarian vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Prothrombin time prolonged (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Transfusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular drainage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Withdrawal of life support (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 988 | click or scan EU-EC-10011828202 | | 2022-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 989 | click or scan EU-EC-10011828096 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 990 | click or scan EU-EC-10011827519 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Unknown - ), Abnormal behaviour (n/a - Unknown - ), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Unknown - ), Hypoxia (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory rate increased (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 991 | click or scan EU-EC-10011827432 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 992 | click or scan EU-EC-10011826580 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 993 | click or scan EU-EC-10011825359 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 994 | click or scan EU-EC-10011825109 | | 2022-03-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 995 | click or scan EU-EC-10011825108 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 996 | click or scan EU-EC-10011825008 | | 2022-03-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypernatraemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 997 | click or scan EU-EC-10011824519 | | 2022-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (3d - Recovered/Resolved - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Somnolence (2d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 998 | click or scan EU-EC-10011824516 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 999 | click or scan EU-EC-10011824474 | | 2022-03-08 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), ICLUSIG [PONATINIB, PONATINIB HYDROCHLORIDE] (S - Chronic myeloid leukaemia - Dose not changed - [n/a - 30mg - Oral]), ICLUSIG [PONATINIB, PONATINIB HYDROCHLORIDE] (S - Chronic myeloid leukaemia - Drug withdrawn - [n/a - 30mg - Oral]), VIDAZA [AZACITIDINE] (S - Chronic myeloid leukaemia - Drug withdrawn - [7d - 1050mg - Subcutaneous]), XEVUDY [SOTROVIMAB] (S - SARS-CoV-2 antibody test - Drug withdrawn - [1d - n/a - Intravenous (not otherwise specified)]) |
| 1000 | click or scan EU-EC-10011824469 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1001 | click or scan EU-EC-10011824447 | | 2022-03-08 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1002 | click or scan EU-EC-10011824434 | | 2022-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Rash (n/a - Recovering/Resolving - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1003 | click or scan EU-EC-10011824411 | | 2022-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Myocarditis (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1004 | click or scan EU-EC-10011824204 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1005 | click or scan EU-EC-10011824156 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Consciousness fluctuating (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 1006 | click or scan EU-EC-10011824006 | | 2022-03-08 | Healthcare Professional | Non EEA | Not Specified | Male | Abdominal discomfort (n/a - Recovered/Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - ), Myocardial injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Toxic cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1007 | click or scan EU-EC-10011824000 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1008 | click or scan EU-EC-10011823930 | | 2022-03-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Breath sounds abnormal (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypopnoea (n/a - Not Recovered/Not Resolved - ), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - ), Speech sound disorder (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1009 | click or scan EU-EC-10011823660 | | 2022-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1010 | click or scan EU-EC-10011823543 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (8d - Fatal - **Results in Death**), Hepatitis (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1011 | click or scan EU-EC-10011823405 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Alopecia (n/a - Unknown - Caused/Prolonged Hospitalisation), Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Atelectasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Bacterial vaginosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Blister (n/a - Unknown - Caused/Prolonged Hospitalisation), Body temperature fluctuation (n/a - Unknown - Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Bone pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac murmur (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Constipation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dry mouth (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysuria (n/a - Unknown - Caused/Prolonged Hospitalisation), Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastric disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Head discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic steatosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Injection site rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung opacity (n/a - Unknown - Caused/Prolonged Hospitalisation), Lupus-like syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Neutropenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Night sweats (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash maculo-papular (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash pruritic (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin discolouration (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Type III immune complex mediated reaction (n/a - Unknown - Caused/Prolonged Hospitalisation), Vitamin D deficiency (n/a - Unknown - Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 1012 | click or scan EU-EC-10011823316 | | 2022-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **1013** | click or scan EU-EC-10011823119 | | 2022-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Gangrene (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Movement disorder (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary retention (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheelchair user (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **1014** | click or scan EU-EC-10011823049 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (7d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **1015** | click or scan EU-EC-10011822631 | | 2022-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Agitation (n/a - Fatal - **Results in Death**), Apnoea (n/a - Fatal - **Results in Death**), Breath sounds abnormal (n/a - Fatal - **Results in Death**), Cheyne-Stokes respiration (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Jugular vein distension (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Moaning (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Stupor (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE)] (S - Product used for unknown indication - Unknown - [n/a - .5mL - Intramuscular]) |
| **1016** | click or scan EU-EC-10011822553 | | 2022-03-08 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **1017** | click or scan EU-EC-10011822298 | | 2022-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Eyelid oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Face oedema (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Oedema peripheral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **1018** | click or scan EU-EC-10011822151 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1019** | click or scan EU-EC-10011822146 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1020** | click or scan EU-EC-10011822097 | | 2022-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (10d - Fatal - **Results in Death**), Death (10d - Fatal - **Results in Death**), Endocarditis (10d - Fatal - **Results in Death**), Gait disturbance (10d - Fatal - **Results in Death**), Iliac artery occlusion (10d - Fatal - **Results in Death**), Monoparesis (10d - Fatal - **Results in Death**), Subarachnoid haemorrhage (10d - Fatal - **Results in Death**), Thrombosis (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1021 | click or scan EU-EC-10011822096 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1022 | click or scan EU-EC-10011822070 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1023 | click or scan EU-EC-10011821922 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1024 | click or scan EU-EC-10011821917 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 1025 | click or scan EU-EC-10011821822 | | 2022-03-08 | Healthcare Professional | Non EEA | Not Specified | Male | Abdominal discomfort (n/a - Recovered/Resolved - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - ), Myocardial injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Toxic cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1026 | click or scan EU-EC-10011821791 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cytokine storm (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Immune system disorder (n/a - Unknown - ), Pulmonary thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1027 | click or scan EU-EC-10011821740 | | 2022-03-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1028 | click or scan EU-EC-10011821499 | | 2022-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (32d - Fatal - **Results in Death**), General physical health deterioration (32d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 1029 | click or scan EU-EC-10011821497 | | 2022-03-08 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 1030 | click or scan EU-EC-10011821493 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **1031** | click or scan EU-EC-10011821152 | | 2022-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Expired product administered (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **1032** | click or scan EU-EC-10011820400 | | 2022-03-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **1033** | click or scan EU-EC-10011820389 | | 2022-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Delusion (n/a - Fatal - **Results in Death**), Depression (n/a - Fatal - **Results in Death**), Major depression (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**), Suicidal ideation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1034** | click or scan EU-EC-10011820388 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1035** | click or scan EU-EC-10011820387 | | 2022-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1036** | click or scan EU-EC-10011820386 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Female | Agitation (4d - Fatal - **Results in Death**), Cyanosis (4d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (4d - Fatal - **Results in Death**), Nervous system disorder (4d - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Peripheral coldness (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1037** | click or scan EU-EC-10011820098 | | 2022-03-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination complication (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **1038** | click or scan EU-EC-10011819304 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (276min - Fatal - **Results in Death**), Dyspnoea (276min - Fatal - **Results in Death**), Haematemesis (276min - Fatal - **Results in Death**), Haemoptysis (276min - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **1039** | click or scan EU-EC-10011818508 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis coronary artery (n/a - Unknown - Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **1040** | click or scan EU-EC-10011818495 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1041 | click or scan EU-EC-10011818460 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1042 | click or scan EU-EC-10011818424 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foreign body in respiratory tract (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1043 | click or scan EU-EC-10011818421 | | 2022-03-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular - More in ICSR]) |
| 1044 | click or scan EU-EC-10011818365 | | 2022-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1045 | click or scan EU-EC-10011818339 | | 2022-03-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | Leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1046 | click or scan EU-EC-10011818286 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1047 | click or scan EU-EC-10011818202 | | 2022-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1048 | click or scan EU-EC-10011817745 | | 2022-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac disorder (153d - Fatal - **Results in Death**), Fatigue (153d - Fatal - **Results in Death**), Headache (153d - Fatal - **Results in Death**), Oedema peripheral (153d - Fatal - **Results in Death**), Oxygen saturation decreased (153d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1049 | click or scan EU-EC-10011817652 | | 2022-03-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**), Dyspnoea (6d - Fatal - **Results in Death**), Headache (6d - Fatal - **Results in Death**), Vaccination site swelling (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1050 | click or scan EU-EC-10011817348 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1051 | click or scan EU-EC-10011817152 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 1052 | click or scan EU-EC-10011817100 | | 2022-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaphylactic reaction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial ischaemia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (1d - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 1053 | click or scan EU-EC-10011817088 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 1054 | click or scan EU-EC-10011817027 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood lactic acid (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain natriuretic peptide (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Imaging procedure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1055 | click or scan EU-EC-10011816802 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1056 | click or scan EU-EC-10011816667 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1057 | click or scan EU-EC-10011816666 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1058 | click or scan EU-EC-10011816661 | | 2022-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Expired product administered (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1059 | click or scan EU-EC-10011816308 | | 2022-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypoaesthesia (n/a - Fatal - **Results in Death**), Vaccination site reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1060 | click or scan EU-EC-10011815762 | | 2022-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1061 | click or scan EU-EC-10011815632 | | 2022-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (13d - Fatal - **Results in Death**), Cough (13d - Fatal - **Results in Death**), Haemoptysis (13d - Fatal - **Results in Death**), Pulmonary embolism (13d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1062 | click or scan EU-EC-10011815127 | | 2022-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1063 | click or scan EU-EC-10011813802 | | 2022-03-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1064 | click or scan EU-EC-10011813717 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1065 | click or scan EU-EC-10011813696 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ill-defined disorder (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1066 | click or scan EU-EC-10011813452 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1067 | click or scan EU-EC-10011813101 | | 2022-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Unknown - ), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Right ventricular failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 1068 | click or scan EU-EC-10011812829 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1069 | click or scan EU-EC-10011812716 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1070 | click or scan EU-EC-10011812714 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypotension (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1071 | click or scan EU-EC-10011812691 | | 2022-03-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1072 | click or scan EU-EC-10011812639 | | 2022-03-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1073 | click or scan EU-EC-10011812615 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1074 | click or scan EU-EC-10011812377 | | 2022-03-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1075 | click or scan EU-EC-10011812354 | | 2022-03-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Periorbital oedema (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 1076 | click or scan EU-EC-10011812200 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gun shot wound (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1077 | click or scan EU-EC-10011812200 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gun shot wound (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1078 | click or scan EU-EC-10011812196 | | 2022-03-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Injection site pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Neurogenic tumour (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1079 | click or scan EU-EC-10011812195 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1080** | click or scan EU-EC-10011811982 | | 2022-03-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **1081** | click or scan EU-EC-10011811490 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - n/a - Intramuscular]) |
| **1082** | click or scan EU-EC-10011811488 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [83d - 1 {DF} - Intramuscular]) |
| **1083** | click or scan EU-EC-10011811485 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [21d - .6mL - Intramuscular]) |
| **1084** | click or scan EU-EC-10011811472 | | 2022-03-07 | Healthcare Professional | EEA | 18-64 Years | Male | Chest discomfort (n/a - Not Recovered/Not Resolved - ), Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **1085** | click or scan EU-EC-10011811443 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **1086** | click or scan EU-EC-10011811405 | | 2022-03-07 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - ), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening), Vaccination failure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **1087** | click or scan EU-EC-10011811393 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (33d - Fatal - **Results in Death**), Vaccination failure (33d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [224d - 1 {DF} - Intramuscular]), DARZALEX 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION [DARATUMUMAB] (S - Plasma cell myeloma - Not applicable - [140d - 1800mg - Subcutaneous]), DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (S - Plasma cell myeloma - Not applicable - [140d - 10mg - Oral]), REVLIMID 5 MG HARD CAPSULES [LENALIDOMIDE] (S - Plasma cell myeloma - Not applicable - [140d - 7.5mg - Oral]), [CASIRIVIMAB, IMDEVIMAB] (S - COVID-19 prophylaxis - Not applicable - [1d - n/a - Intravenous (not otherwise specified)]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1088 | click or scan EU-EC-10011811270 | | 2022-03-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myelodysplastic syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1089 | click or scan EU-EC-10011811251 | | 2022-03-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1090 | click or scan EU-EC-10011811143 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Chronic kidney disease (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1091 | click or scan EU-EC-10011811055 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1092 | click or scan EU-EC-10011811007 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Bronchitis bacterial (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1093 | click or scan EU-EC-10011810854 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1094 | click or scan EU-EC-10011810802 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dementia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1095 | click or scan EU-EC-10011810582 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1096 | click or scan EU-EC-10011810573 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1097 | click or scan EU-EC-10011810462 | | 2022-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1098 | click or scan EU-EC-10011810446 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1099 | click or scan EU-EC-10011810375 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1100 | click or scan EU-EC-10011810316 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1101 | click or scan EU-EC-10011810284 | | 2022-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyslipidaemia (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1102 | click or scan EU-EC-10011810243 | | 2022-03-07 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1103 | click or scan EU-EC-10011810213 | | 2022-03-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Immune system disorder (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Neoplasm progression (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1104 | click or scan EU-EC-10011810025 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1105 | click or scan EU-EC-10011810024 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1106 | click or scan EU-EC-10011810003 | | 2022-03-07 | Healthcare Professional | EEA | 18-64 Years | Male | Acute left ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1107 | click or scan EU-EC-10011809818 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1108 | click or scan EU-EC-10011809702 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1109 | click or scan EU-EC-10011809534 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1110 | click or scan EU-EC-10011809248 | | 2022-03-07 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1111 | click or scan EU-EC-10011809220 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1112 | click or scan EU-EC-10011809194 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1113 | click or scan EU-EC-10011809190 | | 2022-03-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1114 | click or scan EU-EC-10011809006 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1115 | click or scan EU-EC-10011808730 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1116 | click or scan EU-EC-10011808401 | | 2022-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Neuroleptic malignant syndrome (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1117 | click or scan EU-EC-10011807777 | | 2022-03-07 | Healthcare Professional | Non EEA | Not Specified | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1118 | click or scan EU-EC-10011807530 | | 2022-03-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1119 | click or scan EU-EC-10011806674 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1120 | click or scan EU-EC-10011806667 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1121 | click or scan EU-EC-10011806588 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aneurysm ruptured (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Brain stem syndrome (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1122 | click or scan EU-EC-10011806470 | | 2022-03-07 | Healthcare Professional | EEA | 18-64 Years | Male | Hypoventilation (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Obesity (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Still's disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 1123 | click or scan EU-EC-10011806366 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1124 | click or scan EU-EC-10011806299 | | 2022-03-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Body temperature increased (2d - Recovered/Resolved - ), Cerebral haemorrhage (0d - Fatal - **Results in Death**), Necrosis ischaemic (0d - Fatal - **Results in Death**), Petechiae (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1125 | click or scan EU-EC-10011806244 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1126 | click or scan EU-EC-10011805628 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1127 | click or scan EU-EC-10011805370 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Breast neoplasm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Femur fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrooesophageal reflux disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Polyarthritis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1128 | click or scan EU-EC-10011805115 | | 2022-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Feeling hot (n/a - Unknown - ), Induration (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site inflammation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1129 | click or scan EU-EC-10011804804 | | 2022-03-07 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1130 | click or scan EU-EC-10011804771 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Transient ischaemic attack (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Transient ischaemic attack (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1131 | click or scan EU-EC-10011804732 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1132 | click or scan EU-EC-10011804711 | | 2022-03-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1133 | click or scan EU-EC-10011804703 | | 2022-03-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1134 | click or scan EU-EC-10011804702 | | 2022-03-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1135 | click or scan EU-EC-10011804700 | | 2022-03-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Cardiac death (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1136 | click or scan EU-EC-10011804697 | | 2022-03-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1137 | click or scan EU-EC-10011804696 | | 2022-03-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1138 | click or scan EU-EC-10011804688 | | 2022-03-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1139 | click or scan EU-EC-10011804616 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1140 | click or scan EU-EC-10011804487 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1141 | click or scan EU-EC-10011804200 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 1142 | click or scan EU-EC-10011804071 | | 2022-03-07 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1143 | click or scan EU-EC-10011803941 | | 2022-03-07 | Healthcare Professional | EEA | 18-64 Years | Female | Pericarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1144 | click or scan EU-EC-10011803772 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - **Results in Death**), Dizziness (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1145 | click or scan EU-EC-10011803640 | | 2022-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1146 | click or scan EU-EC-10011803637 | | 2022-03-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1147 | click or scan EU-EC-10011803456 | | 2022-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1148 | click or scan EU-EC-10011803427 | | 2022-03-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Troponin T increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1149 | click or scan EU-EC-10011800265 | | 2022-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1150 | click or scan EU-EC-10011800122 | | 2022-03-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cognitive disorder (223d - Fatal - **Results in Death**), Movement disorder (223d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1151 | click or scan EU-EC-10011800118 | | 2022-03-05 | Healthcare Professional | EEA | 65-85 Years | Female | SARS-CoV-2 test positive (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1152 | click or scan EU-EC-10011800116 | | 2022-03-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (12d - Fatal - **Results in Death**), Dehydration (12d - Fatal - **Results in Death**), Oxygen saturation decreased (12d - Fatal - **Results in Death**), SARS-CoV-2 test positive (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1153 | click or scan EU-EC-10011800101 | | 2022-03-05 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure increased (7d - Fatal - **Results in Death**), Cerebral haemorrhage (7d - Fatal - **Results in Death**), Coma (7d - Fatal - **Results in Death**), Headache (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1154 | click or scan EU-EC-10011799968 | | 2022-03-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Retching (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1155 | click or scan EU-EC-10011799917 | | 2022-03-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abnormal loss of weight (87d - Fatal - **Results in Death**), Blood fibrinogen increased (87d - Fatal - **Results in Death**), Blood test abnormal (87d - Fatal - **Results in Death**), Dysphagia (87d - Fatal - **Results in Death**), Dysstasia (87d - Fatal - **Results in Death**), Fibrin D dimer increased (87d - Fatal - **Results in Death**), Lymphadenopathy (87d - Fatal - **Results in Death**), Myalgia (87d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1156 | click or scan EU-EC-10011799387 | | 2022-03-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1157 | click or scan EU-EC-10011799342 | | 2022-03-05 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1158 | click or scan EU-EC-10011798221 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1159 | click or scan EU-EC-10011798171 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Diffuse large B-cell lymphoma (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 1160 | click or scan EU-EC-10011798171 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Diffuse large B-cell lymphoma (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1161 | click or scan EU-EC-10011798034 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN LACTATE] (S - Diarrhoea haemorrhagic - Unknown - [n/a - 500mg - Oral]) |
| 1162 | click or scan EU-EC-10011797552 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1163 | click or scan EU-EC-10011797482 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1164 | click or scan EU-EC-10011797481 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1165 | click or scan EU-EC-10011797377 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1166 | click or scan EU-EC-10011797060 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Malaise (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .25mL - Intramuscular]) |
| 1167 | click or scan EU-EC-10011796919 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Feeling cold (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1168 | click or scan EU-EC-10011796814 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1169 | click or scan EU-EC-10011796422 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Incontinence (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1170 | click or scan EU-EC-10011796128 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1171 | click or scan EU-EC-10011796126 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anticoagulation drug level below therapeutic (n/a - Unknown - ), Encephalomalacia (n/a - Unknown - ), Miller Fisher syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Subacute inflammatory demyelinating polyneuropathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1172 | click or scan EU-EC-10011795977 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Near drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1173 | click or scan EU-EC-10011795896 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 1174 | click or scan EU-EC-10011795762 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1175 | click or scan EU-EC-10011795724 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1176 | click or scan EU-EC-10011795232 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1177 | click or scan EU-EC-10011795218 | | 2022-03-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Idiopathic pulmonary fibrosis (n/a - Fatal - **Results in Death**), Infection (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 1178 | click or scan EU-EC-10011795138 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1179 | click or scan EU-EC-10011795112 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | Eosinophilic myocarditis (n/a - Fatal - **Results in Death**), Haemosiderosis (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1180** | click or scan EU-EC-10011795074 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Intracranial haematoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **1181** | click or scan EU-EC-10011794628 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **1182** | click or scan EU-EC-10011794442 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Follicular lymphoma (641d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **1183** | click or scan EU-EC-10011794417 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **1184** | click or scan EU-EC-10011794082 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Female | Lung adenocarcinoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **1185** | click or scan EU-EC-10011794075 | | 2022-03-04 | Non Healthcare Professional | Non EEA | Not Specified | Male | Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1186** | click or scan EU-EC-10011794006 | | 2022-03-04 | Healthcare Professional | EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1187** | click or scan EU-EC-10011793886 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **1188** | click or scan EU-EC-10011793836 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .25mL - Intramuscular]) |
| **1189** | click or scan EU-EC-10011793835 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Colon cancer (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1190** | click or scan EU-EC-10011793778 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic hepatitis B (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ischaemic stroke (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **1191** | click or scan EU-EC-10011793668 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **1192** | click or scan EU-EC-10011793335 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **1193** | click or scan EU-EC-10011793314 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **1194** | click or scan EU-EC-10011793292 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Quadriparesis (n/a - Unknown - Other Medically Important Condition), Serum ferritin increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1195** | click or scan EU-EC-10011793251 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1196** | click or scan EU-EC-10011793247 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain natriuretic peptide increased (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea at rest (n/a - Unknown - Other Medically Important Condition), Electrocardiogram abnormal (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Right atrial enlargement (n/a - Unknown - ), Right ventricular enlargement (n/a - Unknown - ), Right ventricular hypertrophy (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1197** | click or scan EU-EC-10011793238 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Agonal respiration (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Myocardial fibrosis (n/a - Unknown - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Presyncope (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Vasodilatation (n/a - Unknown - ), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1198 | click or scan EU-EC-10011793225 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Obstructive airways disorder (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1199 | click or scan EU-EC-10011793208 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1200 | click or scan EU-EC-10011793206 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Emotional distress (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1201 | click or scan EU-EC-10011793176 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1202 | click or scan EU-EC-10011792998 | | 2022-03-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1203 | click or scan EU-EC-10011792951 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1204 | click or scan EU-EC-10011792847 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Unknown]) |
| 1205 | click or scan EU-EC-10011792502 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1206 | click or scan EU-EC-10011792490 | | 2022-03-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1207 | click or scan EU-EC-10011792430 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1208 | click or scan EU-EC-10011792423 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Lung cancer metastatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1209 | click or scan EU-EC-10011792369 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Liver abscess (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peritonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1210 | click or scan EU-EC-10011791995 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1211 | click or scan EU-EC-10011791909 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1212 | click or scan EU-EC-10011791839 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1213 | click or scan EU-EC-10011791580 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1214 | click or scan EU-EC-10011791556 | | 2022-03-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1215 | click or scan EU-EC-10011791554 | | 2022-03-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1216 | click or scan EU-EC-10011791551 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1217 | click or scan EU-EC-10011791547 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1218 | click or scan EU-EC-10011791538 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1219 | click or scan EU-EC-10011791394 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1220 | click or scan EU-EC-10011791302 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | Lung carcinoma cell type unspecified stage IV (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1221 | click or scan EU-EC-10011791058 | | 2022-03-04 | Healthcare Professional | EEA | More than 85 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1222 | click or scan EU-EC-10011790980 | | 2022-03-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1223 | click or scan EU-EC-10011790966 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1224 | click or scan EU-EC-10011790965 | | 2022-03-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1225 | click or scan EU-EC-10011790953 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1226 | click or scan EU-EC-10011790952 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1227 | click or scan EU-EC-10011790947 | | 2022-03-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1228 | click or scan EU-EC-10011790833 | | 2022-03-04 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1229 | click or scan EU-EC-10011790516 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1230 | click or scan EU-EC-10011790454 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1231 | click or scan EU-EC-10011790152 | | 2022-03-04 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1232 | click or scan EU-EC-10011789978 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Female | Breast cancer metastatic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1233 | click or scan EU-EC-10011789817 | | 2022-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1234 | click or scan EU-EC-10011789778 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Alanine aminotransferase increased (11d - Recovered/Resolved - ), Aspartate aminotransferase increased (11d - Recovered/Resolved - ), Blood creatine phosphokinase increased (n/a - Unknown - ), Blood creatinine increased (n/a - Recovering/Resolving - ), Blood urea increased (11d - Recovered/Resolved - ), C-reactive protein increased (11d - Recovered/Resolved - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Constipation (n/a - Unknown - ), Gallbladder polyp (n/a - Unknown - ), Haemoglobin decreased (n/a - Not Recovered/Not Resolved - ), Hepatic cyst (n/a - Unknown - ), Hepatic function abnormal (11d - Recovered/Resolved - Other Medically Important Condition), Hypertension (n/a - Unknown - ), Legionella test positive (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (11d - Recovered/Resolved - ), Pneumonia aspiration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia legionella (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Streptococcus test positive (n/a - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 1235 | click or scan EU-EC-10011789711 | | 2022-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Disease risk factor (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1236 | click or scan EU-EC-10011788080 | | 2022-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Unknown - ), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cavernous sinus thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral artery thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral mass effect (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eye pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic cerebellar infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic transformation stroke (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hepatic enzyme abnormal (n/a - Unknown - ), Inflammatory marker increased (n/a - Unknown - ), Monoparesis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ophthalmic vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupil fixed (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sinusitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**), Venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 1237 | click or scan EU-EC-10011788025 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Insomnia (n/a - Unknown - ), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nasal congestion (n/a - Not Recovered/Not Resolved - ), Nasal inflammation (n/a - Unknown - ), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rhinorrhoea (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA VIRUS] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1238 | click or scan EU-EC-10011788025 | | 2022-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Insomnia (n/a - Unknown - ), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nasal congestion (n/a - Not Recovered/Not Resolved - ), Nasal inflammation (n/a - Unknown - ), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rhinorrhoea (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA VIRUS] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1239 | click or scan EU-EC-10011788024 | | 2022-03-04 | Non Healthcare Professional | Non EEA | Not Specified | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1240 | click or scan EU-EC-10011786172 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Autoimmune hepatitis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1241 | click or scan EU-EC-10011785865 |  | 2022-03-03 | Healthcare Professional | EEA | Not Specified | Female | Drug interaction (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Myelodysplastic syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Terminal state (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (I - COVID-19 immunisation - Unknown - [1d - n/a - n/a]), OLAPARIB [OLAPARIB] (I - BRCA1 gene mutation, Ovarian cancer - Drug withdrawn - [1mo - n/a - Oral]) |
| 1242 | click or scan EU-EC-10011785847 |  | 2022-03-03 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1243 | click or scan EU-EC-10011785810 |  | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bone cancer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain neoplasm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatic carcinoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Small cell carcinoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1244 | click or scan EU-EC-10011785117 |  | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Altered state of consciousness (n/a - Fatal - **Results in Death**), Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haematoma (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Recovered/Resolved - ), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1245 | click or scan EU-EC-10011785053 |  | 2022-03-03 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1246 | click or scan EU-EC-10011784628 |  | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | Lung cancer metastatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1247 | click or scan EU-EC-10011784372 |  | 2022-03-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Multiple sclerosis relapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 1248 | click or scan EU-EC-10011784233 |  | 2022-03-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1249 | click or scan EU-EC-10011784040 | | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1250 | click or scan EU-EC-10011783994 | | 2022-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dehydration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1251 | click or scan EU-EC-10011783948 | | 2022-03-03 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1252 | click or scan EU-EC-10011783947 | | 2022-03-03 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1253 | click or scan EU-EC-10011783940 | | 2022-03-03 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1254 | click or scan EU-EC-10011783927 | | 2022-03-03 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1255 | click or scan EU-EC-10011783642 | | 2022-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 1256 | click or scan EU-EC-10011783611 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1257 | click or scan EU-EC-10011783338 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Breast cancer metastatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1258 | click or scan EU-EC-10011783327 | | 2022-03-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hemiplegia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1259 | click or scan EU-EC-10011783208 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1260 | click or scan EU-EC-10011783208 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1261 | click or scan EU-EC-10011782692 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1262 | click or scan EU-EC-10011782644 | | 2022-03-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [229d - 1 {DF} - Intramuscular]) |
| 1263 | click or scan EU-EC-10011782566 | | 2022-03-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1264 | click or scan EU-EC-10011782557 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Henoch-Schonlein purpura (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1265 | click or scan EU-EC-10011782205 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1266 | click or scan EU-EC-10011782177 | | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1267 | click or scan EU-EC-10011782133 | | 2022-03-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1268 | click or scan EU-EC-10011781794 | | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Male | Abnormal loss of weight (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain stem infarction (n/a - Unknown - ), Condition aggravated (n/a - Fatal - **Results in Death**), Coordination abnormal (n/a - Not Recovered/Not Resolved - ), Diplopia (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysmetria (n/a - Unknown - ), Fall (n/a - Recovered/Resolved With Sequelae - ), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - ), Hiccups (n/a - Recovering/Resolving - ), Humerus fracture (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - ), Nerve compression (n/a - Unknown - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sensory loss (n/a - Unknown - ), Sensory loss (n/a - Unknown - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Walking disability (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1269 | click or scan EU-EC-10011781694 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1270 | click or scan EU-EC-10011781692 | | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1271 | click or scan EU-EC-10011781570 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1272 | click or scan EU-EC-10011781562 | | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1273 | click or scan EU-EC-10011781561 | | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1274 | click or scan EU-EC-10011781558 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1275 | click or scan EU-EC-10011781557 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1276 | click or scan EU-EC-10011781364 | | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1277 | click or scan EU-EC-10011781346 | | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1278 | click or scan EU-EC-10011781138 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1279 | click or scan EU-EC-10011781100 | | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1280 | click or scan EU-EC-10011780844 | | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Radiation pneumonitis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), OPDIVO [NIVOLUMAB] (S - Oesophageal carcinoma - Unknown - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 1281 | click or scan EU-EC-10011780838 | | 2022-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiration abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1282 | click or scan EU-EC-10011780836 | | 2022-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - Intramuscular]) |
| 1283 | click or scan EU-EC-10011780833 | | 2022-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Generalised oedema (n/a - Unknown - ), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1284 | click or scan EU-EC-10011780832 | | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | C-reactive protein increased (n/a - Unknown - ), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Other Medically Important Condition), Oedema (n/a - Unknown - ), Palpitations (n/a - Unknown - ), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1285 | click or scan EU-EC-10011780820 |  | 2022-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1286 | click or scan EU-EC-10011780187 |  | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Non-Hodgkin's lymphoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1287 | click or scan EU-EC-10011780104 |  | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Suspected COVID-19 (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1288 | click or scan EU-EC-10011780024 |  | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (9d - Fatal - **Results in Death**), Cerebrovascular accident (10d - Fatal - **Results in Death**), Seizure (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1289 | click or scan EU-EC-10011780010 |  | 2022-03-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chills (3mo - Not Recovered/Not Resolved - Life Threatening), Fatigue (3mo - Not Recovered/Not Resolved - Life Threatening), Myalgia (3mo - Not Recovered/Not Resolved - Life Threatening), Neoplasm (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (3mo - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 1290 | click or scan EU-EC-10011779911 |  | 2022-03-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 1291 | click or scan EU-EC-10011779841 |  | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1292 | click or scan EU-EC-10011779745 |  | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Asymptomatic COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiopulmonary failure (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1293 | click or scan EU-EC-10011779727 |  | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Hypotension (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1294 | click or scan EU-EC-10011779438 |  | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | Cachexia (n/a - Fatal - **Results in Death**), Prostate cancer (n/a - Fatal - **Results in Death**), Small cell lung cancer (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1295 | click or scan EU-EC-10011779224 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1296 | click or scan EU-EC-10011779110 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (0d - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1297 | click or scan EU-EC-10011779101 | | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Female | Cachexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1298 | click or scan EU-EC-10011779036 | | 2022-03-03 | Non Healthcare Professional | EEA | Not Specified | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1299 | click or scan EU-EC-10011778884 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1300 | click or scan EU-EC-10011778870 | | 2022-03-03 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Small cell lung cancer metastatic (52d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 1301 | click or scan EU-EC-10011778830 | | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1302 | click or scan EU-EC-10011778829 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1303 | click or scan EU-EC-10011778828 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1304 | click or scan EU-EC-10011778761 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1305 | click or scan EU-EC-10011778730 | | 2022-03-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1306 | click or scan EU-EC-10011778451 | | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1307 | click or scan EU-EC-10011778450 | | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1308 | click or scan EU-EC-10011778449 | | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1309 | click or scan EU-EC-10011778448 | | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1310 | click or scan EU-EC-10011778447 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1311 | click or scan EU-EC-10011778431 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Malignant neoplasm progression (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1312 | click or scan EU-EC-10011778300 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (0d - Fatal - **Results in Death**), Cardiogenic shock (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1313 | click or scan EU-EC-10011778291 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1314 | click or scan EU-EC-10011778277 | | 2022-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1315 | click or scan EU-EC-10011778099 |  | 2022-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | Bronchiolitis (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1316 | click or scan EU-EC-10011778078 |  | 2022-03-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Unknown - ), Back pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Neoplasm malignant (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1317 | click or scan EU-EC-10011777294 |  | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | C-reactive protein increased (n/a - Unknown - ), Cardiac dysfunction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Electrocardiogram Q wave abnormal (n/a - Unknown - Other Medically Important Condition), Extrasystoles (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - ), Supraventricular tachycardia (n/a - Unknown - ), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1318 | click or scan EU-EC-10011777129 |  | 2022-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Generalised oedema (n/a - Unknown - ), Left ventricular dysfunction (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1319 | click or scan EU-EC-10011775694 |  | 2022-03-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [1d - 1 {DF} - Unknown]) |
| 1320 | click or scan EU-EC-10011775634 |  | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 1321 | click or scan EU-EC-10011775571 |  | 2022-03-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neurological symptom (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 1322 | click or scan EU-EC-10011775096 |  | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Poriomania (n/a - Unknown - ), Wound (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1323 | click or scan EU-EC-10011774991 |  | 2022-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1324 | click or scan EU-EC-10011774964 | | 2022-03-03 | Healthcare Professional | EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebellar haematoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 1325 | click or scan EU-EC-10011774597 | | 2022-03-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Acute kidney injury (66d - Fatal - **Results in Death**), Alveolitis (66d - Fatal - **Results in Death**), Arthralgia (66d - Fatal - **Results in Death**), Cardiac arrest (66d - Fatal - **Results in Death**), Conjunctival hyperaemia (66d - Fatal - **Results in Death**), Joint swelling (66d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (66d - Fatal - **Results in Death**), Pain in extremity (66d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 1326 | click or scan EU-EC-10011772782 | | 2022-03-02 | Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Hypersensitivity (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 1327 | click or scan EU-EC-10011772704 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1328 | click or scan EU-EC-10011772426 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral arterial occlusive disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 1329 | click or scan EU-EC-10011772411 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Haematemesis (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 1330 | click or scan EU-EC-10011772328 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 1331 | click or scan EU-EC-10011772165 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1332 | click or scan EU-EC-10011770599 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Female | Amputation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Carotid artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dysarthria (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Muscular weakness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vision blurred (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1333 | click or scan EU-EC-10011770511 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1334 | click or scan EU-EC-10011770090 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1335 | click or scan EU-EC-10011769197 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Subdural haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1336 | click or scan EU-EC-10011769184 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1337 | click or scan EU-EC-10011768962 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Immunisation (0d - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1338 | click or scan EU-EC-10011768658 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure congestive (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1339 | click or scan EU-EC-10011768411 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | Left ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1340 | click or scan EU-EC-10011768168 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | Immunisation (n/a - Fatal - **Results in Death**), Left ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1341 | click or scan EU-EC-10011768051 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Arteriosclerosis coronary artery (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1342 | click or scan EU-EC-10011767855 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Male | Metastases to bone (n/a - Fatal - **Results in Death**), Renal cancer (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1343 | click or scan EU-EC-10011767836 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1344 | click or scan EU-EC-10011767798 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**), Immunisation (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1345 | click or scan EU-EC-10011767139 | | 2022-03-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1346 | click or scan EU-EC-10011767129 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1347 | click or scan EU-EC-10011767129 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1348 | click or scan EU-EC-10011767090 | | 2022-03-02 | Non Healthcare Professional | EEA | More than 85 Years | Male | Influenza like illness (n/a - Unknown - ), Myocardial infarction (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Nausea (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1349 | click or scan EU-EC-10011767089 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 immunisation (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**), Immunisation (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1350 | click or scan EU-EC-10011766861 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1351 | click or scan EU-EC-10011766657 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1352 | click or scan EU-EC-10011766173 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1353 | click or scan EU-EC-10011765821 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1354 | click or scan EU-EC-10011765752 | | 2022-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1355 | click or scan EU-EC-10011765746 | | 2022-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1356 | click or scan EU-EC-10011765496 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Cor pulmonale (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1357 | click or scan EU-EC-10011765348 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1358 | click or scan EU-EC-10011765320 | | 2022-03-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Drug interaction (n/a - Unknown - ), Myasthenia gravis (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (S - Myasthenia gravis - n/a - [n/a - n/a - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [PYRIDOSTIGMINE BROMIDE] (S - Myasthenia gravis - n/a - [n/a - n/a - n/a]) |
| 1359 | click or scan EU-EC-10011764664 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | Asymptomatic COVID-19 (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1360 | click or scan EU-EC-10011764457 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemoperitoneum (n/a - Fatal - **Results in Death**), Uterine rupture (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1361 | click or scan EU-EC-10011764456 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1362 | click or scan EU-EC-10011764117 | | 2022-03-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Interchange of vaccine products (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1363 | click or scan EU-EC-10011764117 | | 2022-03-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Interchange of vaccine products (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1364 | click or scan EU-EC-10011764087 | | 2022-03-02 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nephrostomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nosocomial infection (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Papilloma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ureteric obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 1365 | click or scan EU-EC-10011764023 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1366 | click or scan EU-EC-10011763914 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular insufficiency (0d - Fatal - **Results in Death**), Respiratory failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1367 | click or scan EU-EC-10011763886 | | 2022-03-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 1368 | click or scan EU-EC-10011763808 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Lateral medullary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1369 | click or scan EU-EC-10011763807 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1370 | click or scan EU-EC-10011763372 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1371 | click or scan EU-EC-10011763156 | | 2022-03-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Pulmonary oedema (117d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1372 | click or scan EU-EC-10011762694 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Papillary muscle rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) |
| 1373 | click or scan EU-EC-10011762465 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Unknown - Life Threatening), Coronary artery thrombosis (n/a - Unknown - Life Threatening), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 1374 | click or scan EU-EC-10011762456 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1375 | click or scan EU-EC-10011762361 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal loss of weight (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Blood glucose increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Night sweats (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tuberculosis (1mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1376 | click or scan EU-EC-10011759479 | | 2022-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1377 | click or scan EU-EC-10011759394 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1378 | click or scan EU-EC-10011758959 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1379 | click or scan EU-EC-10011758103 | | 2022-03-02 | Healthcare Professional | EEA | 18-64 Years | Female | Arrhythmia (0d - Fatal - **Results in Death**), Asthenia (10d - Fatal - **Results in Death**), COVID-19 (0d - Fatal - **Results in Death**), Cardiogenic shock (0d - Fatal - **Results in Death**), Fatigue (10d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1380 | click or scan EU-EC-10011757980 | | 2022-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cyanosis (n/a - Unknown - ), Face oedema (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1381 | click or scan EU-EC-10011757819 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1382 | click or scan EU-EC-10011757819 | | 2022-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1383 | click or scan EU-EC-10011757474 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1384 | click or scan EU-EC-10011757379 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | ARANESP [DARBEPOETIN ALFA] (S - Myelodysplastic syndrome - Not applicable - [n/a - n/a - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) |
| 1385 | click or scan EU-EC-10011757063 | | 2022-03-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Paralysis (n/a - Unknown - Disabling), Pulmonary embolism (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 1386 | click or scan EU-EC-10011756713 | | 2022-03-02 | Non Healthcare Professional | EEA | 18-64 Years | Female | Aortic valve stenosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac tamponade (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Emphysema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Goitre (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Jugular vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Metastases to lung (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Metastases to lymph nodes (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Metastases to neck (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Metastatic neoplasm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Poorly differentiated thyroid carcinoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 1387 | click or scan EU-EC-10011756473 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1388 | click or scan EU-EC-10011756456 | | 2022-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1389 | click or scan EU-EC-10011756371 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthma (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1390 | click or scan EU-EC-10011755504 | | 2022-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | AST/ALT ratio (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Adrenal insufficiency (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Alanine aminotransferase normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anaemia macrocytic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anion gap (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anxiety (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspartate aminotransferase normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacteraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Basophil count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Basophil percentage decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bilirubin conjugated normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood albumin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood alkaline phosphatase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bilirubin normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood calcium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood chloride increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactate dehydrogenase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood magnesium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood osmolarity decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood phosphorus decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea nitrogen/creatinine ratio (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carbon dioxide normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coagulation test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1391 | click or scan EU-EC-10011755368 | | 2022-03-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1392 | click or scan EU-EC-10011755367 | | 2022-03-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1393 | click or scan EU-EC-10011755362 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | Stent-graft endoleak (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1394 | click or scan EU-EC-10011755361 | | 2022-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebellar haemorrhage (22d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1395 | click or scan EU-EC-10011754978 | | 2022-03-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1396 | click or scan EU-EC-10011754407 | | 2022-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1397 | click or scan EU-EC-10011754337 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1398 | click or scan EU-EC-10011753680 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (10d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1399 | click or scan EU-EC-10011753532 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1400 | click or scan EU-EC-10011752523 | | 2022-03-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Heart disease congenital (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Stillbirth (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1401 | click or scan EU-EC-10011752457 | | 2022-03-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1402 | click or scan EU-EC-10011752380 | | 2022-03-01 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1403 | click or scan EU-EC-10011752250 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1404 | click or scan EU-EC-10011752249 | | 2022-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1405 | click or scan EU-EC-10011752077 | | 2022-03-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 1406 | click or scan EU-EC-10011751940 | | 2022-03-01 | Healthcare Professional | EEA | More than 85 Years | Female | Left ventricular failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - n/a]) |
| 1407 | click or scan EU-EC-10011751913 | | 2022-03-01 | Healthcare Professional | EEA | More than 85 Years | Female | Aortic dissection (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1408 | click or scan EU-EC-10011751178 | | 2022-03-01 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (48h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1409 | click or scan EU-EC-10011751175 | | 2022-03-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Quadriparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [196d - 1 {DF} - Intramuscular]) |
| 1410 | click or scan EU-EC-10011751141 | | 2022-03-01 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), ELIQUIS [APIXABAN] (S - Atrial fibrillation - Drug withdrawn - [n/a - n/a - Oral]), [FLECAINIDE ACETATE] (S - Atrial fibrillation - Drug withdrawn - [n/a - n/a - Oral]), [FUROSEMIDE] (S - Product used for unknown indication - Drug withdrawn - [n/a - n/a - Oral]) |
| 1411 | click or scan EU-EC-10011751065 | | 2022-03-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [26d - 1 {DF} - Intramuscular]) |
| 1412 | click or scan EU-EC-10011751061 | | 2022-03-01 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1413 | click or scan EU-EC-10011750249 | | 2022-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - ), Hypoaesthesia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1414 | click or scan EU-EC-10011750231 | | 2022-03-01 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sleep apnoea syndrome (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1415 | click or scan EU-EC-10011750194 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Refusal of treatment by patient (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]) |
| 1416 | click or scan EU-EC-10011749938 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1417 | click or scan EU-EC-10011749733 | | 2022-03-01 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1418 | click or scan EU-EC-10011749632 | | 2022-03-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 100ug - Intramuscular]) |
| 1419 | click or scan EU-EC-10011749468 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1420 | click or scan EU-EC-10011749235 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1421 | click or scan EU-EC-10011749230 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Retinal artery occlusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1422 | click or scan EU-EC-10011748920 | | 2022-03-01 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 1423 | click or scan EU-EC-10011748904 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Chronic kidney disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1424 | click or scan EU-EC-10011748814 | | 2022-03-01 | Healthcare Professional | EEA | 65-85 Years | Female | Left ventricular failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1425 | click or scan EU-EC-10011748694 | | 2022-03-01 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (4d - Fatal - **Results in Death**), Pulmonary embolism (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1426 | click or scan EU-EC-10011747994 | | 2022-03-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 4{DF} - n/a]) |
| 1427 | click or scan EU-EC-10011747807 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1428 | click or scan EU-EC-10011747147 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1429 | click or scan EU-EC-10011747146 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haematoma (n/a - Unknown - ), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1430 | click or scan EU-EC-10011746726 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Accelerated hypertension (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1431 | click or scan EU-EC-10011746724 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1432 | click or scan EU-EC-10011746708 | | 2022-03-01 | Healthcare Professional | EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**), Tenderness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1433** | click or scan EU-EC-10011746561 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cellulitis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **1434** | click or scan EU-EC-10011746560 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **1435** | click or scan EU-EC-10011746448 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **1436** | click or scan EU-EC-10011746346 | | 2022-03-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain lower (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bladder cancer recurrent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eczema (n/a - Unknown - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **1437** | click or scan EU-EC-10011746339 | | 2022-03-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **1438** | click or scan EU-EC-10011746335 | | 2022-03-01 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **1439** | click or scan EU-EC-10011746314 | | 2022-03-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **1440** | click or scan EU-EC-10011746254 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Medication error (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Threat of redundancy - Not applicable - [n/a - n/a - Intramuscular]) |
| **1441** | click or scan EU-EC-10011746184 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1442 | click or scan EU-EC-10011745985 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1443 | click or scan EU-EC-10011745982 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Subdural haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1444 | click or scan EU-EC-10011745908 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1445 | click or scan EU-EC-10011745857 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Adenocarcinoma metastatic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Epistaxis (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral ischaemia (n/a - Fatal - **Results in Death**), Prosthetic cardiac valve thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Skin haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 1446 | click or scan EU-EC-10011745815 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary mass (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 1447 | click or scan EU-EC-10011745666 | | 2022-03-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dementia (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Oedema (n/a - Unknown - ), Rash macular (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 1448 | click or scan EU-EC-10011745605 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1449 | click or scan EU-EC-10011745366 |  | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acidosis (n/a - Fatal - **Results in Death**), Angiogram pulmonary normal (n/a - Fatal - **Results in Death**), Anticoagulant therapy (n/a - Fatal - **Results in Death**), Anuria (n/a - Fatal - **Results in Death**), Arterial catheterisation (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Bacteraemia (n/a - Fatal - **Results in Death**), Bladder catheterisation (n/a - Fatal - **Results in Death**), Blood bicarbonate increased (n/a - Fatal - **Results in Death**), Blood culture positive (n/a - Fatal - **Results in Death**), Blood gases (n/a - Fatal - **Results in Death**), Blood glucose increased (n/a - Fatal - **Results in Death**), Blood triglycerides increased (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Carbon dioxide increased (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Central venous catheterisation (n/a - Fatal - **Results in Death**), Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Constipation (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Culture negative (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dialysis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Enteral nutrition (n/a - Fatal - **Results in Death**), Fluid balance negative (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Hypercapnia (n/a - Fatal - **Results in Death**), Hyperkalaemia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Laboratory test normal (n/a - Fatal - **Results in Death**), Leukocytosis (n/a - Fatal - **Results in Death**), Mechanical ventilation (n/a - Fatal - **Results in Death**), Mechanical ventilation complication (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Polyuria (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rectal tube insertion (n/a - Fatal - **Results in Death**), Renal impairment (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Staphylococcus test positive (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Transfusion (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1450 | click or scan EU-EC-10011745136 |  | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1451 | click or scan EU-EC-10011745135 |  | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1452 | click or scan EU-EC-10011745028 |  | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1453 | click or scan EU-EC-10011745028 |  | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1454 | click or scan EU-EC-10011744823 |  | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1455 | click or scan EU-EC-10011744800 | | 2022-03-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pollakiuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1456 | click or scan EU-EC-10011744799 | | 2022-03-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Autoimmune thyroiditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Breast swelling (n/a - Unknown - ), Neuroendocrine carcinoma metastatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - ), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), White blood cell count decreased (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 1457 | click or scan EU-EC-10011744590 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1458 | click or scan EU-EC-10011744420 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1459 | click or scan EU-EC-10011744419 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1460 | click or scan EU-EC-10011744389 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1461 | click or scan EU-EC-10011744388 | | 2022-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1462 | click or scan EU-EC-10011744347 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Hepatic function abnormal (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Renal impairment (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Other]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1463 | click or scan EU-EC-10011744310 | | 2022-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1464 | click or scan EU-EC-10011744137 | | 2022-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1465 | click or scan EU-EC-10011743642 | | 2022-03-01 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (2d - Fatal - **Results in Death**), Facial spasm (2d - Fatal - **Results in Death**), Hemiparesis (2d - Fatal - **Results in Death**), Loss of consciousness (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1466 | click or scan EU-EC-10011741154 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1467 | click or scan EU-EC-10011741145 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1468 | click or scan EU-EC-10011741052 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1469 | click or scan EU-EC-10011741037 | | 2022-02-28 | Healthcare Professional | EEA | 18-64 Years | Female | Brain compression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain stem syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venous occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Unknown - [n/a - n/a - Intramuscular]) |
| 1470 | click or scan EU-EC-10011740974 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1471 | click or scan EU-EC-10011740720 | | 2022-02-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1472 | click or scan EU-EC-10011740701 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1473 | click or scan EU-EC-10011740699 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1474 | click or scan EU-EC-10011740635 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1475 | click or scan EU-EC-10011740612 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1476 | click or scan EU-EC-10011740573 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1477 | click or scan EU-EC-10011740572 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1478 | click or scan EU-EC-10011740490 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1479 | click or scan EU-EC-10011740489 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Accelerated hypertension (n/a - Fatal - **Results in Death**), Acute pulmonary oedema (n/a - Fatal - **Results in Death**), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1480 | click or scan EU-EC-10011740485 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1481 | click or scan EU-EC-10011740481 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1482 | click or scan EU-EC-10011740476 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1483 | click or scan EU-EC-10011740121 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1484 | click or scan EU-EC-10011740065 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1485 | click or scan EU-EC-10011740011 |  | 2022-02-28 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 1486 | click or scan EU-EC-10011739905 |  | 2022-02-28 | Healthcare Professional | EEA | More than 85 Years | Female | Melaena (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]) |
| 1487 | click or scan EU-EC-10011739880 |  | 2022-02-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1488 | click or scan EU-EC-10011739376 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1489 | click or scan EU-EC-10011739249 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1490 | click or scan EU-EC-10011739127 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1491 | click or scan EU-EC-10011739054 |  | 2022-02-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1492 | click or scan EU-EC-10011739011 |  | 2022-02-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1493 | click or scan EU-EC-10011738753 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Insomnia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 1494 | click or scan EU-EC-10011738675 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), LEVOFLOXACIN [LEVOFLOXACIN] (S - n/a - Not applicable - [n/a - n/a - Oral]), [CEFTRIAXONE SODIUM] (S - n/a - Not applicable - [n/a - 1g - Intravenous (not otherwise specified)]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE HYDROGEN SUCCINATE, METHYLPREDNISOLONE SODIUM SUCCINATE] (S - n/a - Not applicable - [n/a - 80mg - Intravenous (not otherwise specified)]), [PREDNISOLONE] (S - n/a - Not applicable - [n/a - 10mg - Intravenous (not otherwise specified)]) |
| 1495 | click or scan EU-EC-10011738353 | | 2022-02-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1496 | click or scan EU-EC-10011738321 | | 2022-02-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disability (n/a - Unknown - Disabling), Feeding disorder (n/a - Unknown - ), Gait inability (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Walking disability (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1497 | click or scan EU-EC-10011738177 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Aortic dissection (n/a - Fatal - **Results in Death**), Ventricular septal defect (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 1498 | click or scan EU-EC-10011737696 | | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1499 | click or scan EU-EC-10011737678 | | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Male | Mallory-Weiss syndrome (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 1500 | click or scan EU-EC-10011737633 | | 2022-02-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1501 | click or scan EU-EC-10011737632 |  | 2022-02-28 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular - More in ICSR]) |
| 1502 | click or scan EU-EC-10011737600 |  | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 1503 | click or scan EU-EC-10011737566 |  | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 1504 | click or scan EU-EC-10011737532 |  | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 1505 | click or scan EU-EC-10011737108 |  | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1506 | click or scan EU-EC-10011737047 |  | 2022-02-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Disease progression (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Prostate cancer (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Unknown - [n/a - n/a - Intramuscular]), [LEUPRORELIN, LEUPRORELIN ACETATE] (S - Prostate cancer - Unknown - [n/a - n/a - Subcutaneous]) |
| 1507 | click or scan EU-EC-10011736824 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic perforation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac hypertrophy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Overdose (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Unknown]) |
| 1508 | click or scan EU-EC-10011736821 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1509 | click or scan EU-EC-10011736814 |  | 2022-02-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1510 | click or scan EU-EC-10011736813 |  | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Unknown - ), Haemorrhoids (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**), Pulmonary tuberculosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1511 | click or scan EU-EC-10011736796 | | 2022-02-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1512 | click or scan EU-EC-10011736793 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1513 | click or scan EU-EC-10011736790 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**), Pleural neoplasm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1514 | click or scan EU-EC-10011736744 | | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - ), Hypoxia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Infection (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (3h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Restlessness (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | CASIRIVIMAB, IMDEVIMAB [CASIRIVIMAB, IMDEVIMAB] (S - COVID-19 - Not applicable - [30min - 1200mg - Intravenous (not otherwise specified)]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1515 | click or scan EU-EC-10011736741 | | 2022-02-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Alanine aminotransferase increased (n/a - Unknown - ), Aspartate aminotransferase increased (n/a - Unknown - ), Base excess decreased (n/a - Unknown - ), Blood albumin decreased (n/a - Unknown - ), Blood bicarbonate decreased (n/a - Unknown - ), Blood chloride decreased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - ), Blood lactic acid increased (n/a - Unknown - ), Blood potassium increased (n/a - Unknown - ), Blood sodium decreased (n/a - Unknown - ), Blood urea decreased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardiac disorder (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematocrit decreased (n/a - Unknown - ), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Mean cell volume increased (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), PCO2 increased (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Protein total decreased (n/a - Unknown - ), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Troponin I increased (n/a - Unknown - ), pH body fluid decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1516 | click or scan EU-EC-10011736730 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1517 | click or scan EU-EC-10011736725 | | 2022-02-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Obstructive airways disorder (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1518 | click or scan EU-EC-10011736724 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Intracranial aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1519 | click or scan EU-EC-10011736712 | | 2022-02-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Local reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1520 | click or scan EU-EC-10011736599 | | 2022-02-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1521 | click or scan EU-EC-10011736503 | | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1522 | click or scan EU-EC-10011736477 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1523 | click or scan EU-EC-10011736401 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Airway peak pressure increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hallucination (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoglycaemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1524 | click or scan EU-EC-10011736017 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 1525 | click or scan EU-EC-10011736016 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Unknown - Life Threatening), Leptospirosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Unknown - Life Threatening), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Overdose (n/a - Fatal - **Results in Death**), Scrub typhus (n/a - Unknown - Life Threatening), Seizure (n/a - Unknown - Life Threatening), Sepsis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Severe fever with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 1526 | click or scan EU-EC-10011735996 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1527 | click or scan EU-EC-10011735974 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Discomfort (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1528 | click or scan EU-EC-10011735953 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Eye injury (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 1529 | click or scan EU-EC-10011735825 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cognitive disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 1530 | click or scan EU-EC-10011735463 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Near drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 1531 | click or scan EU-EC-10011735036 | | 2022-02-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | ARANESP [DARBEPOETIN ALFA] (S - Product used for unknown indication - n/a - [1d - n/a - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 1532 | click or scan EU-EC-10011734276 | | 2022-02-28 | Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain herniation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 immunisation (n/a - Unknown - ), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pupils unequal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 1533 | click or scan EU-EC-10011734236 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 1534 | click or scan EU-EC-10011734001 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Body temperature increased (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Death (0d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Pulmonary embolism (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1535 | click or scan EU-EC-10011733933 | | 2022-02-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Aspiration (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Drooping shoulder syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysarthria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Eyelid ptosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intensive care (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Movement disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tongue paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1536 | click or scan EU-EC-10011733795 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1537 | click or scan EU-EC-10011733701 | | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1538 | click or scan EU-EC-10011733428 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1539 | click or scan EU-EC-10011732490 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1540 | click or scan EU-EC-10011732483 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1541 | click or scan EU-EC-10011732460 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Gastric ulcer haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1542 | click or scan EU-EC-10011732450 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1543 | click or scan EU-EC-10011732395 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1544 | click or scan EU-EC-10011732263 | | 2022-02-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1545 | click or scan EU-EC-10011731641 | | 2022-02-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Recovered/Resolved - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1546 | click or scan EU-EC-10011731596 | | 2022-02-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypoaesthesia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1547 | click or scan EU-EC-10011731575 | | 2022-02-28 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1548 | click or scan EU-EC-10011731573 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1549 | click or scan EU-EC-10011731572 | | 2022-02-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1550 | click or scan EU-EC-10011731570 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1551 | click or scan EU-EC-10011731569 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1552 | click or scan EU-EC-10011731566 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1553 | click or scan EU-EC-10011731565 | | 2022-02-28 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Generalised oedema (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1554 | click or scan EU-EC-10011731550 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1555 | click or scan EU-EC-10011731548 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1556 | click or scan EU-EC-10011731496 | | 2022-02-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Exercise electrocardiogram abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 1557 | click or scan EU-EC-10011731482 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 1558 | click or scan EU-EC-10011731157 | | 2022-02-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1559 | click or scan EU-EC-10011730884 | | 2022-02-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1560 | click or scan EU-EC-10011730554 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1mL - Intramuscular]) |
| 1561 | click or scan EU-EC-10011730424 | | 2022-02-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1562 | click or scan EU-EC-10011730213 | | 2022-02-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1563 | click or scan EU-EC-10011730145 | | 2022-02-28 | Healthcare Professional | EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Memory impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1564 | click or scan EU-EC-10011729269 | | 2022-02-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (35d - Recovered/Resolved - ), COVID-19 (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (35d - Recovered/Resolved - ), Gastrointestinal haemorrhage (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin decreased (35d - Recovered/Resolved - ), Hypotension (35d - Recovered/Resolved - ), Nausea (35d - Recovered/Resolved - ), Vaccination failure (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]), XARELTO 15 MG FILM-COATED TABLETS [RIVAROXABAN] (S - n/a - Not applicable - [n/a - 15mg - Oral]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1565 | click or scan EU-EC-10011726307 |  | 2022-02-26 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1566 | click or scan EU-EC-10011726278 |  | 2022-02-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea exertional (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 1567 | click or scan EU-EC-10011726244 |  | 2022-02-26 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1568 | click or scan EU-EC-10011725901 |  | 2022-02-26 | Healthcare Professional | EEA | 18-64 Years | Female | Jaundice (39d - Fatal - **Results in Death**), Presyncope (39d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1569 | click or scan EU-EC-10011725711 |  | 2022-02-26 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral ischaemia (4d - Fatal - **Results in Death**), Loss of consciousness (4d - Fatal - **Results in Death**), Pleural effusion (4d - Fatal - **Results in Death**), Rib fracture (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 1570 | click or scan EU-EC-10011725649 |  | 2022-02-26 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Necrotising fasciitis (0d - Fatal - **Results in Death**), Oedema (0d - Fatal - **Results in Death**), Pain in extremity (0d - Fatal - **Results in Death**), Subcutaneous emphysema (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1571 | click or scan EU-EC-10011725353 |  | 2022-02-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1572 | click or scan EU-EC-10011725050 |  | 2022-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1573 | click or scan EU-EC-10011724894 |  | 2022-02-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1574 | click or scan EU-EC-10011724438 |  | 2022-02-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (222d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1575 | click or scan EU-EC-10011724169 | | 2022-02-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 1576 | click or scan EU-EC-10011724143 | | 2022-02-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1577 | click or scan EU-EC-10011724141 | | 2022-02-25 | Healthcare Professional | Non EEA | Not Specified | Female | Chest pain (n/a - Unknown - Other Medically Important Condition), Chronic kidney disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1578 | click or scan EU-EC-10011723941 | | 2022-02-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | RAPAMUNE [SIROLIMUS] (S - Prophylaxis against transplant rejection - Dose not changed - [n/a - 1mg - n/a]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1579 | click or scan EU-EC-10011723646 | | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Organising pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1580 | click or scan EU-EC-10011723616 | | 2022-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1581 | click or scan EU-EC-10011723607 | | 2022-02-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1582 | click or scan EU-EC-10011723522 | | 2022-02-25 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1583 | click or scan EU-EC-10011723052 | | 2022-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Idiopathic pulmonary fibrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1584 | click or scan EU-EC-10011722620 | | 2022-02-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Foetal death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1585 | click or scan EU-EC-10011722441 | | 2022-02-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1586 | click or scan EU-EC-10011722354 | | 2022-02-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1587 | click or scan EU-EC-10011721532 | | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 1588 | click or scan EU-EC-10011721442 | | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [215d - 3 {DF} - Intramuscular]) |
| 1589 | click or scan EU-EC-10011721434 | | 2022-02-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1590 | click or scan EU-EC-10011721231 | | 2022-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1591 | click or scan EU-EC-10011720975 | | 2022-02-25 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Embolism (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1592 | click or scan EU-EC-10011720914 | | 2022-02-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pallor (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1593 | click or scan EU-EC-10011720459 | | 2022-02-25 | Healthcare Professional | EEA | 18-64 Years | Female | Activated partial thromboplastin time shortened (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Homans' sign positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immobile (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1594 | click or scan EU-EC-10011720261 | | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1595** | click or scan<br>EU-EC-10011720083 |  | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**), Cardiac failure (14d - Fatal - **Results in Death**), Cardio-respiratory arrest (14d - Fatal - **Results in Death**), Death (14d - Fatal - **Results in Death**), Decreased appetite (14d - Fatal - **Results in Death**), Dependence on oxygen therapy (14d - Fatal - **Results in Death**), Disturbance in social behaviour (14d - Fatal - **Results in Death**), Faeces soft (14d - Fatal - **Results in Death**), General physical health deterioration (14d - Fatal - **Results in Death**), Pleural effusion (14d - Fatal - **Results in Death**), SARS-CoV-2 test positive (7d - Fatal - **Results in Death**), Somnolence (14d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1596** | click or scan<br>EU-EC-10011719981 |  | 2022-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Unknown - ), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Unknown - ), Pneumonia aspiration (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| | | | | | | | | | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN, A/BRISBANE/10/2007 (H3N2)-LIKE STRAIN, B/FLORIDA/4/2006-LIKE STRAIN, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/VICTORIA/361/2011 (H3N2)â€“DERIVED STRAIN USED (IVR-165), B/WISCONSIN/1/2010-LIKE STRAIN USED (NYMC BX-39) DERIVED FROM B/HUBEI-WUJIAGANG/158/2009, A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/MOSCOW/10/99 (H3N2) - LIKE STRAIN (A/PANAMA/2007/99 REASS. RESVIR-17), B/SICHUAN/379/99-LIKE STRAIN (B/JOHANNESBURG/5/99), A/SOUTH AUSTRALIA/55/2014 STRAIN, A/SWITZERLAND/9715293/2013 (H3N2) - LIKE STRAIN (A/SOUTH AUSTRALIA/55/2014, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09 - |

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| # | EU Local Number | | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT (Duration - Outcome - Seriousness Criteria) | Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route) |
|---|---|---|---|---|---|---|---|---|---|
| **1597** | click or scan<br>EU-EC-10011719969 | | 2022-02-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, B/MASSACHUSETTS/02/2012, A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, A/VICTORIA/361/2011 (H3N2)â€“DERIVED STRAIN USED (IVR-165), B/WISCONSIN/1/2010-LIKE STRAIN USED (NYMC BX-39) DERIVED FROM B/HUBEI-WUJIAGANG/158/2009, A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, A/WISCONSIN/67/2005 (H3N2), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN, B/MALAYSIA/2506/2004 - LIKE STRAIN, B/BEIJING/184/93-LIKE STRAIN (B/YAMANASHI/166/98), A/SYDNEY/5/97 (H3N2)-LIKE STRAIN (A/SYDNEY/5/97 REASS. RESVIR 13), A/BEIJING/262/95 (H1N1) - LIKE STRAIN (A/BEIJING/262/95 REASS. X-127), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1), A/PERTH/16/2009 (H3N2) - LIKE STRAIN, B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009(H1N1)-LIKE STRAIN (NYMC X-179A), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NIB-65), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009(H1N1)-LIKE STRAIN (NYMC X-179A), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327), B/MASSACHUSETTS/02/2012, A/TEXAS/50/2012 (H3N2) â€“ DERIVED STRAIN USED (NYMC X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE STRAIN, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SOUTH AUSTRALIA/55/2014, IVR-175), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **1598** | click or scan<br>EU-EC-10011719739 | | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (53d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (49d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1599** | click or scan EU-EC-10011719732 | | 2022-02-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bradykinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Memory impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **1600** | click or scan EU-EC-10011719697 | | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1601** | click or scan EU-EC-10011719585 | | 2022-02-25 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1602** | click or scan EU-EC-10011719549 | | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1603** | click or scan EU-EC-10011719509 | | 2022-02-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Amnesia (n/a - Unknown - ), Aphasia (n/a - Unknown - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Condition aggravated (n/a - Unknown - ), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **1604** | click or scan EU-EC-10011719499 | | 2022-02-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Herpes zoster (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1605** | click or scan EU-EC-10011719383 | | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1606** | click or scan EU-EC-10011719191 | | 2022-02-25 | Healthcare Professional | EEA | Not Specified | Not Specified | Exposure during pregnancy (n/a - Fatal - **Results in Death**), Foetal death (n/a - Fatal - **Results in Death**), Preterm premature rupture of membranes (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1607** | click or scan EU-EC-10011719040 | | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **1608** | click or scan EU-EC-10011719037 | | 2022-02-25 | Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1609 | click or scan EU-EC-10011718896 |  | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1610 | click or scan EU-EC-10011718342 |  | 2022-02-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1611 | click or scan EU-EC-10011718312 |  | 2022-02-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1612 | click or scan EU-EC-10011718203 |  | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1613 | click or scan EU-EC-10011718202 |  | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1614 | click or scan EU-EC-10011718201 |  | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1615 | click or scan EU-EC-10011717620 |  | 2022-02-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Lung neoplasm malignant (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1616 | click or scan EU-EC-10011717614 |  | 2022-02-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1617 | click or scan EU-EC-10011717613 |  | 2022-02-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1618 | click or scan EU-EC-10011717612 |  | 2022-02-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cough (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Not Recovered/Not Resolved - ), Hypophagia (n/a - Not Recovered/Not Resolved - ), Oral candidiasis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1619 | click or scan EU-EC-10011717600 |  | 2022-02-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (90min - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Tachypnoea (90min - Fatal - **Results in Death**), Urinary retention (90min - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Intramuscular]) |
| 1620 | click or scan EU-EC-10011717590 |  | 2022-02-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1621 | click or scan EU-EC-10011717580 |  | 2022-02-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic inflammatory demyelinating polyradiculoneuropathy (52d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 1622 | click or scan EU-EC-10011717486 |  | 2022-02-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1623 | click or scan EU-EC-10011717147 |  | 2022-02-25 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic aneurysm rupture (1s - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1624 | click or scan EU-EC-10011716364 |  | 2022-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1625 | click or scan EU-EC-10011716079 |  | 2022-02-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1626 | click or scan EU-EC-10011716069 |  | 2022-02-25 | Healthcare Professional | Non EEA | Not Specified | Male | Foetal exposure during pregnancy (1d - Recovered/Resolved - ), Premature baby death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Transplacental]) |
| 1627 | click or scan EU-EC-10011715588 |  | 2022-02-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug interaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoptysis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral swelling (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Small cell lung cancer metastatic (153d - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (I - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (I - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Parenteral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (I - Hypertension - Drug withdrawn - [144d - 5mg - Oral]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1628** | click or scan EU-EC-10011714709 | | 2022-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood creatinine increased (n/a - Unknown - Other Medically Important Condition), Colitis (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Hepatotoxicity (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Life Threatening, Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Myositis (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Life Threatening, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a - n/a - n/a]), PEMBROLIZUMAB [PEMBROLIZUMAB] (S - Small intestine carcinoma metastatic - Unknown - [n/a - 400mg - n/a]) |
| **1629** | click or scan EU-EC-10011714560 | | 2022-02-25 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**), Drug ineffective (7d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **1630** | click or scan EU-EC-10011713559 | | 2022-02-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (47d - Fatal - **Results in Death**), Acute kidney injury (47d - Fatal - **Results in Death**), Asthenia (47d - Fatal - **Results in Death**), Burning sensation (47d - Fatal - **Results in Death**), Dysstasia (47d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **1631** | click or scan EU-EC-10011713501 | | 2022-02-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **1632** | click or scan EU-EC-10011712323 | | 2022-02-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dermatomyositis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1633** | click or scan EU-EC-10011711986 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (5min - Fatal - **Results in Death**), COVID-19 (5min - Fatal - **Results in Death**), Clavicle fracture (5min - Fatal - **Results in Death**), Dyspnoea (5min - Fatal - **Results in Death**), Loss of consciousness (5min - Fatal - **Results in Death**), Rib fracture (5min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **1634** | click or scan EU-EC-10011711475 | | 2022-02-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE] (S - Hypertension - Not applicable - [1472d - n/a - n/a]) |
| **1635** | click or scan EU-EC-10011711371 | | 2022-02-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Atrioventricular block complete (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **1636** | click or scan EU-EC-10011710819 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Nausea (55d - Recovered/Resolved - ), Pyrexia (55d - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1637 | click or scan EU-EC-10011710288 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1638 | click or scan EU-EC-10011709938 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1639 | click or scan EU-EC-10011709938 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1640 | click or scan EU-EC-10011709763 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypertensive urgency (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1641 | click or scan EU-EC-10011709424 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1642 | click or scan EU-EC-10011709015 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1643 | click or scan EU-EC-10011709013 | | 2022-02-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Body temperature increased (990min - Recovered/Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Heart rate increased (n/a - Not Recovered/Not Resolved - ), Impaired work ability (n/a - Unknown - ), Inflammation (n/a - Fatal - **Results in Death**), Left ventricular dysfunction (n/a - Fatal - **Results in Death**), Myalgia (n/a - Not Recovered/Not Resolved - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oropharyngeal pain (n/a - Recovered/Resolved - ), Product use issue (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - ), Tachycardia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [1d - n/a - n/a]) |
| 1644 | click or scan EU-EC-10011708636 | | 2022-02-24 | Healthcare Professional | Non EEA | Not Specified | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1645 | click or scan EU-EC-10011708613 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1646 | click or scan EU-EC-10011708601 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1647 | click or scan EU-EC-10011708544 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1648 | click or scan EU-EC-10011708410 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Chills (n/a - Unknown - ), Fall (n/a - Unknown - ), Nausea (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1649 | click or scan EU-EC-10011708223 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - 1 {DF} - Intramuscular]) |
| 1650 | click or scan EU-EC-10011708217 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [3d - 3 {DF} - Intramuscular]) |
| 1651 | click or scan EU-EC-10011708213 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [217d - 1 {DF} - Intramuscular]), DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (S - Plasma cell myeloma - Not applicable - [n/a - n/a - Oral]), REVLIMID [LENALIDOMIDE] (S - Plasma cell myeloma - Not applicable - [n/a - n/a - Oral]), [CYCLOPHOSPHAMIDE] (S - Plasma cell myeloma - Not applicable - [n/a - n/a - Oral]) |
| 1652 | click or scan EU-EC-10011708212 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), METHOTREXATE [METHOTREXATE] (S - Rheumatoid arthritis - Not applicable - [n/a - 10mg - Unknown]) |
| 1653 | click or scan EU-EC-10011708187 | | 2022-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - 2 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1654 | click or scan EU-EC-10011707642 |  | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pruritus (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1655 | click or scan EU-EC-10011707540 |  | 2022-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1656 | click or scan EU-EC-10011707509 |  | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1657 | click or scan EU-EC-10011707499 |  | 2022-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypercholesterolaemia (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1658 | click or scan EU-EC-10011707491 |  | 2022-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Faeces discoloured (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1659 | click or scan EU-EC-10011707488 |  | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1660 | click or scan EU-EC-10011706872 |  | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1661 | click or scan EU-EC-10011706870 |  | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1662 | click or scan EU-EC-10011706562 |  | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1663 | click or scan EU-EC-10011706516 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Stillbirth (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1664 | click or scan EU-EC-10011706479 | | 2022-02-24 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 1665 | click or scan EU-EC-10011706297 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Blood glucose fluctuation (n/a - Unknown - ), Circulatory collapse (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Gastrointestinal pain (n/a - Unknown - ), Haematochezia (n/a - Unknown - ), Headache (n/a - Unknown - ), Rectal haemorrhage (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Sinusitis (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1666 | click or scan EU-EC-10011706080 | | 2022-02-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1667 | click or scan EU-EC-10011706079 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1668 | click or scan EU-EC-10011706076 | | 2022-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1669 | click or scan EU-EC-10011706028 | | 2022-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (30min - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1670 | click or scan EU-EC-10011705957 | | 2022-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1671 | click or scan EU-EC-10011705794 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1672 | click or scan EU-EC-10011705543 | | 2022-02-24 | Healthcare Professional | EEA | 18-64 Years | Female | Fall (n/a - Fatal - **Results in Death**), Malaise (4d - Recovering/Resolving - ), Myalgia (4d - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1673 | click or scan EU-EC-10011704894 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Encephalitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Miller Fisher syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1674 | click or scan EU-EC-10011704850 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Disturbance in attention (n/a - Fatal - **Results in Death**), Food refusal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 1675 | click or scan EU-EC-10011704731 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 1676 | click or scan EU-EC-10011704432 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Intraventricular haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 1677 | click or scan EU-EC-10011704338 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (0d - Recovered/Resolved - ), Diabetes mellitus inadequate control (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5{DF} - Intramuscular]) |
| 1678 | click or scan EU-EC-10011704145 | | 2022-02-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1679 | click or scan EU-EC-10011703998 | | 2022-02-24 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1680 | click or scan EU-EC-10011703934 | | 2022-02-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1681 | click or scan EU-EC-10011703644 | | 2022-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1682 | click or scan EU-EC-10011703568 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Underdose (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR]) |
| 1683 | click or scan EU-EC-10011703534 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1684 | click or scan EU-EC-10011703455 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (2d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1685 | click or scan EU-EC-10011703120 | | 2022-02-24 | Healthcare Professional | EEA | More than 85 Years | Male | Azotaemia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacterial test (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**), Dehydration (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Stupor (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 1686 | click or scan EU-EC-10011703079 | | 2022-02-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1687 | click or scan EU-EC-10011702855 | | 2022-02-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Myocardial ischaemia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1688 | click or scan EU-EC-10011702488 | | 2022-02-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1689 | click or scan EU-EC-10011702415 | | 2022-02-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Central nervous system lesion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1690 | click or scan EU-EC-10011702375 | | 2022-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 1691 | click or scan EU-EC-10011702049 | | 2022-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1692 | click or scan EU-EC-10011701830 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary alveolar haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1693 | click or scan EU-EC-10011701717 | | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1694 | click or scan EU-EC-10011701477 |  | 2022-02-24 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1695 | click or scan EU-EC-10011701022 |  | 2022-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1696 | click or scan EU-EC-10011700493 |  | 2022-02-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Contusion (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination complication (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 1697 | click or scan EU-EC-10011700409 |  | 2022-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 1698 | click or scan EU-EC-10011699800 |  | 2022-02-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arrhythmia supraventricular (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Ventricular arrhythmia (n/a - Fatal - **Results in Death**), Ventricular extrasystoles (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .25mL - Intramuscular]) |
| 1699 | click or scan EU-EC-10011698120 |  | 2022-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1700 | click or scan EU-EC-10011697815 |  | 2022-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory tract infection (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 1701 | click or scan EU-EC-10011697810 |  | 2022-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 1702 | click or scan EU-EC-10011697807 |  | 2022-02-23 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory failure (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 1703 | click or scan EU-EC-10011697671 |  | 2022-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (26d - Fatal - **Results in Death**), General physical health deterioration (52d - Fatal - **Results in Death**), Somnolence (52d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **1704** | click or scan EU-EC-10011697656 |  | 2022-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (61d - Fatal - **Results in Death**), Cardiac failure (61d - Fatal - **Results in Death**), Haematuria (61d - Fatal - **Results in Death**), Productive cough (61d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **1705** | click or scan EU-EC-10011697649 |  | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac tamponade (65d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericardial effusion (65d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **1706** | click or scan EU-EC-10011697638 |  | 2022-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **1707** | click or scan EU-EC-10011697635 |  | 2022-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **1708** | click or scan EU-EC-10011697563 |  | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Male | Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **1709** | click or scan EU-EC-10011696524 |  | 2022-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1710** | click or scan EU-EC-10011696523 |  | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Male | Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Endocarditis (n/a - Fatal - **Results in Death**), Staphylococcal infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1711** | click or scan EU-EC-10011696504 |  | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Unknown - ), Epistaxis (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1712** | click or scan EU-EC-10011695858 |  | 2022-02-23 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Foetal chromosome abnormality (4mo - Fatal - **Results in Death**, Congenital Anomaly), Foetal malformation (4mo - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure timing unspecified (4mo - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **1713** | click or scan EU-EC-10011695834 | | 2022-02-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Autoimmune disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Full blood count abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Night sweats (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Serum ferritin increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Still's disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1714** | click or scan EU-EC-10011695830 | | 2022-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebellar haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Device dislocation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Partial seizures (n/a - Unknown - Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **1715** | click or scan EU-EC-10011695537 | | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Female | Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1716** | click or scan EU-EC-10011694952 | | 2022-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1717** | click or scan EU-EC-10011694585 | | 2022-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain herniation (n/a - Fatal - **Results in Death**), Cerebrovascular disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **1718** | click or scan EU-EC-10011694505 | | 2022-02-23 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **1719** | click or scan EU-EC-10011694395 | | 2022-02-23 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [41d - 2{DF} - Intramuscular]) |
| **1720** | click or scan EU-EC-10011694371 | | 2022-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1721 | click or scan EU-EC-10011694319 | | 2022-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blood pressure fluctuation (n/a - Unknown - Other Medically Important Condition), Brain oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Hypokinesia (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Puncture site pain (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1722 | click or scan EU-EC-10011694186 | | 2022-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Insomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1723 | click or scan EU-EC-10011693268 | | 2022-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1724 | click or scan EU-EC-10011692784 | | 2022-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemothorax (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1725 | click or scan EU-EC-10011692776 | | 2022-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Diabetes mellitus (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 1726 | click or scan EU-EC-10011692684 | | 2022-02-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1727 | click or scan EU-EC-10011692486 | | 2022-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1728 | click or scan EU-EC-10011692244 | | 2022-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Atrioventricular block (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1729 | click or scan EU-EC-10011692235 | | 2022-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ataxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - ), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1730 | click or scan EU-EC-10011691979 | | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Female | Pain in extremity (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1731 | click or scan EU-EC-10011691648 | | 2022-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hydrocephalus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 1732 | click or scan EU-EC-10011691471 | | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 1733 | click or scan EU-EC-10011691136 | | 2022-02-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Viral pericarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1734 | click or scan EU-EC-10011690590 | | 2022-02-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1735 | click or scan EU-EC-10011690336 | | 2022-02-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1736 | click or scan EU-EC-10011690283 | | 2022-02-23 | Non Healthcare Professional | Non EEA | Not Specified | Female | Pharyngeal swelling (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1737 | click or scan EU-EC-10011690160 | | 2022-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1738 | click or scan EU-EC-10011690095 | | 2022-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Breast pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1739 | click or scan EU-EC-10011689743 | | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1740 | click or scan EU-EC-10011689338 | | 2022-02-23 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1741 | click or scan EU-EC-10011688963 | | 2022-02-23 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1742 | click or scan EU-EC-10011688918 | | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Female | Amputation (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Carotid artery thrombosis (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dysarthria (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Muscular weakness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Peripheral artery thrombosis (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Respiratory arrest (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vision blurred (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1743 | click or scan EU-EC-10011688693 | | 2022-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Pyrexia (2d - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular - More in ICSR]) |
| 1744 | click or scan EU-EC-10011688692 | | 2022-02-23 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia viral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1745 | click or scan EU-EC-10011688381 | | 2022-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1746 | click or scan EU-EC-10011687378 | | 2022-02-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dysaesthesia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1747 | click or scan EU-EC-10011686996 | | 2022-02-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |
| 1748 | click or scan EU-EC-10011685048 | | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1749 | click or scan EU-EC-10011685028 | | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .25mL - Intramuscular]) |
| 1750 | click or scan EU-EC-10011684787 | | 2022-02-22 | Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1751 | click or scan EU-EC-10011684397 | | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .25mL - Intramuscular - More in ICSR]) |
| 1752 | click or scan EU-EC-10011684338 | | 2022-02-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 1753 | click or scan EU-EC-10011684148 | | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1754 | click or scan EU-EC-10011683988 | | 2022-02-22 | Healthcare Professional | Non EEA | Not Specified | Female | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Right ventricular dysfunction (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 1755 | click or scan EU-EC-10011683731 | | 2022-02-22 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1756 | click or scan EU-EC-10011683696 | | 2022-02-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Disease recurrence (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malignant nervous system neoplasm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tuberculosis of central nervous system (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1757 | click or scan EU-EC-10011682997 | | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral mass effect (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cervical radiculopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug abuse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Escherichia test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Face oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperammonaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupils unequal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal replacement therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rheumatoid arthritis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sputum culture positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcus test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine output decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1758 | click or scan EU-EC-10011682726 | | 2022-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1759 | click or scan EU-EC-10011682206 | | 2022-02-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1760 | click or scan EU-EC-10011681658 | | 2022-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1761 | click or scan EU-EC-10011681654 | | 2022-02-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1762 | click or scan EU-EC-10011681636 | | 2022-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1763 | click or scan EU-EC-10011681411 | | 2022-02-22 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1764 | click or scan EU-EC-10011681312 | | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1765 | click or scan EU-EC-10011681270 | | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Female | Intestinal ischaemia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1766 | click or scan EU-EC-10011681227 | | 2022-02-22 | Healthcare Professional | EEA | More than 85 Years | Female | Dehydration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1767 | click or scan EU-EC-10011680324 | | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1768 | click or scan EU-EC-10011679817 | | 2022-02-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1769 | click or scan EU-EC-10011679798 | | 2022-02-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1770 | click or scan EU-EC-10011679682 | | 2022-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heat illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1771 | click or scan EU-EC-10011679193 | | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 1772 | click or scan EU-EC-10011679037 | | 2022-02-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Vascular stent thrombosis (n/a - Fatal - **Results in Death**), Vascular stent thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1773 | click or scan EU-EC-10011677628 | | 2022-02-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1774 | click or scan EU-EC-10011677046 | | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Male | Agranulocytosis (n/a - Fatal - **Results in Death**), Anaemia (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Pneumocystis jirovecii pneumonia (n/a - Fatal - **Results in Death**), Pulmonary mucormycosis (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 1775 | click or scan EU-EC-10011676678 | | 2022-02-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Embolic stroke (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1776 | click or scan EU-EC-10011676408 | | 2022-02-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1777 | click or scan EU-EC-10011676407 | | 2022-02-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dementia (n/a - Fatal - **Results in Death**), Microangiopathy (n/a - Fatal - **Results in Death**), Neuroleptic-induced deficit syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1778 | click or scan EU-EC-10011676404 | | 2022-02-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1779 | click or scan EU-EC-10011676401 |  | 2022-02-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1780 | click or scan EU-EC-10011676264 |  | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Female | Neoplasm malignant (115d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 1781 | click or scan EU-EC-10011675513 |  | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1782 | click or scan EU-EC-10011675323 |  | 2022-02-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1783 | click or scan EU-EC-10011675311 |  | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1784 | click or scan EU-EC-10011675117 |  | 2022-02-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1785 | click or scan EU-EC-10011675106 |  | 2022-02-22 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Dysuria (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (3d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 1786 | click or scan EU-EC-10011674963 |  | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1787 | click or scan EU-EC-10011674941 |  | 2022-02-22 | Healthcare Professional | EEA | 18-64 Years | Male | Bronchiolitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Bronchitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericardial effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Right ventricular dilatation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1788 | click or scan EU-EC-10011674786 |  | 2022-02-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1789 | click or scan EU-EC-10011674785 | | 2022-02-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1790 | click or scan EU-EC-10011674783 | | 2022-02-22 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1791 | click or scan EU-EC-10011674777 | | 2022-02-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Balance disorder (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1792 | click or scan EU-EC-10011674776 | | 2022-02-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1793 | click or scan EU-EC-10011674693 | | 2022-02-22 | Healthcare Professional | EEA | 18-64 Years | Male | Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 1794 | click or scan EU-EC-10011674547 | | 2022-02-22 | Healthcare Professional | EEA | 65-85 Years | Male | Colitis ischaemic (n/a - Fatal - **Results in Death**), Glioblastoma (n/a - Fatal - **Results in Death**), Neurological symptom (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 1795 | click or scan EU-EC-10011673951 | | 2022-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac murmur (n/a - Recovered/Resolved - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1796 | click or scan EU-EC-10011673828 | | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1797 | click or scan EU-EC-10011673770 | | 2022-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1798 | click or scan EU-EC-10011673586 | | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1799 | click or scan EU-EC-10011673586 | | 2022-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1800 | click or scan EU-EC-10011671326 |  | 2022-02-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1801 | click or scan EU-EC-10011671044 |  | 2022-02-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1802 | click or scan EU-EC-10011670566 |  | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (0d - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (0d - Fatal - **Results in Death**, Other Medically Important Condition), Near drowning (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1803 | click or scan EU-EC-10011670415 |  | 2022-02-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Balance disorder (n/a - Fatal - **Results in Death**), Blindness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Metastasis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Optic nerve injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Fatal - **Results in Death**), Photophobia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1804 | click or scan EU-EC-10011669769 |  | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1805 | click or scan EU-EC-10011669709 |  | 2022-02-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1806 | click or scan EU-EC-10011668910 |  | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Sudden cardiac death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1807 | click or scan EU-EC-10011668546 |  | 2022-02-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sleep disorder (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [CLOZAPINE] (S - Sleep disorder, Stress - Unknown - [n/a - 100mg - Oral]) |
| 1808 | click or scan EU-EC-10011668491 |  | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1809 | click or scan EU-EC-10011668489 | | 2022-02-21 | Healthcare Professional | EEA | 65-85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Subcutaneous]) |
| 1810 | click or scan EU-EC-10011668480 | | 2022-02-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Intraventricular haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 1811 | click or scan EU-EC-10011668443 | | 2022-02-21 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1812 | click or scan EU-EC-10011668366 | | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (17d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1813 | click or scan EU-EC-10011668292 | | 2022-02-21 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 1814 | click or scan EU-EC-10011667738 | | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1815 | click or scan EU-EC-10011667334 | | 2022-02-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bacterial infection (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1816 | click or scan EU-EC-10011667172 | | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 1817 | click or scan EU-EC-10011666827 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arrhythmia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriosclerosis (n/a - Unknown - ), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal atrophy (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1818 | click or scan EU-EC-10011666592 | | 2022-02-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1819 | click or scan EU-EC-10011666566 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1820 | click or scan EU-EC-10011666566 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1821 | click or scan EU-EC-10011666325 | | 2022-02-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1822 | click or scan EU-EC-10011665801 | | 2022-02-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1823 | click or scan EU-EC-10011665768 | | 2022-02-21 | Healthcare Professional | EEA | 65-85 Years | Female | Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 antibody test negative (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1824 | click or scan EU-EC-10011665698 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1825 | click or scan EU-EC-10011665697 | | 2022-02-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Overdose (n/a - Unknown - ), Pyrexia (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 100ug - Intramuscular]) |
| 1826 | click or scan EU-EC-10011665468 | | 2022-02-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Not Recovered/Not Resolved - Life Threatening), Cerebrovascular accident (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Life Threatening), Death (0d - Fatal - **Results in Death**), Hemiparesis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1827 | click or scan EU-EC-10011665350 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1828 | click or scan EU-EC-10011664871 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arrhythmia (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1829 | click or scan EU-EC-10011664586 | | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1830 | click or scan EU-EC-10011664388 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Ischaemic stroke (20d - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1mL - Intramuscular]) |
| 1831 | click or scan EU-EC-10011664306 | | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1832 | click or scan EU-EC-10011664304 | | 2022-02-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1833 | click or scan EU-EC-10011664086 | | 2022-02-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1834 | click or scan EU-EC-10011663874 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anosmia (4d - Fatal - **Results in Death**), Dizziness (4d - Fatal - **Results in Death**), Pain (4d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1835 | click or scan EU-EC-10011662424 | | 2022-02-21 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1836 | click or scan EU-EC-10011662416 | | 2022-02-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac failure congestive (n/a - Unknown - Other Medically Important Condition), Collagen disorder (n/a - Unknown - ), Fall (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Hydronephrosis (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition), Movement disorder (n/a - Unknown - ), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ovarian cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Polymyositis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Urinary tract infection (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1837 | click or scan EU-EC-10011662339 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1838 | click or scan EU-EC-10011662229 | | 2022-02-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1839 | click or scan EU-EC-10011661724 |  | 2022-02-21 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure acute (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suspected COVID-19 (1d - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1840 | click or scan EU-EC-10011661671 |  | 2022-02-21 | Healthcare Professional | EEA | 18-64 Years | Male | Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Spontaneous bacterial peritonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1841 | click or scan EU-EC-10011661462 |  | 2022-02-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypersensitivity (n/a - Fatal - **Results in Death**), Lid sulcus deepened (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1842 | click or scan EU-EC-10011661301 |  | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 1843 | click or scan EU-EC-10011661228 |  | 2022-02-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Inappropriate schedule of product administration (n/a - Unknown - ), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1844 | click or scan EU-EC-10011661217 |  | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (n/a - Fatal - **Results in Death**), Presyncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1845 | click or scan EU-EC-10011660959 |  | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1846 | click or scan EU-EC-10011660897 |  | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1847 | click or scan EU-EC-10011660851 |  | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 1848 | click or scan EU-EC-10011660806 |  | 2022-02-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypoaesthesia (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1849** | click or scan EU-EC-10011660484 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Intramuscular]) |
| **1850** | click or scan EU-EC-10011660386 | | 2022-02-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **1851** | click or scan EU-EC-10011660165 | | 2022-02-21 | Healthcare Professional | EEA | 65-85 Years | Female | Post cardiac arrest syndrome (9d - Fatal - **Results in Death**), Respiratory acidosis (9d - Fatal - **Results in Death**), SARS-CoV-2 test positive (9d - Fatal - **Results in Death**), Sopor (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **1852** | click or scan EU-EC-10011660055 | | 2022-02-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (9d - Fatal - **Results in Death**), Loss of consciousness (9d - Fatal - **Results in Death**), Thrombosis (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **1853** | click or scan EU-EC-10011658903 | | 2022-02-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **1854** | click or scan EU-EC-10011657276 | | 2022-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (6d - Fatal - **Results in Death**), Aphasia (6d - Fatal - **Results in Death**), Bladder sphincter atony (6d - Fatal - **Results in Death**), Cerebrovascular accident (6d - Fatal - **Results in Death**), Coma (6d - Fatal - **Results in Death**), Pneumonia (6d - Fatal - **Results in Death**), Respiratory failure (6d - Fatal - **Results in Death**), Septic shock (6d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |
| **1855** | click or scan EU-EC-10011657275 | | 2022-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (10d - Fatal - **Results in Death**), Confusional state (10d - Fatal - **Results in Death**), Disorientation (10d - Fatal - **Results in Death**), Hypoxia (10d - Fatal - **Results in Death**), Respiratory failure (10d - Fatal - **Results in Death**), Septic shock (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **1856** | click or scan EU-EC-10011657272 | | 2022-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (12d - Fatal - **Results in Death**), Cardiomegaly (12d - Fatal - **Results in Death**), Generalised oedema (12d - Fatal - **Results in Death**), Shock (12d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |
| **1857** | click or scan EU-EC-10011657192 | | 2022-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Hyperhidrosis (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**), Orthopnoea (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .25mL - Intramuscular]), FLUAD TETRA [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Influenza immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1858** | click or scan EU-EC-10011656944 |  | 2022-02-19 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **1859** | click or scan EU-EC-10011655660 |  | 2022-02-18 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1860** | click or scan EU-EC-10011655221 |  | 2022-02-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (164d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **1861** | click or scan EU-EC-10011654356 |  | 2022-02-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Productive cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **1862** | click or scan EU-EC-10011654112 |  | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute hepatic failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic function abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Upper gastrointestinal haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1863** | click or scan<br>EU-EC-10011653863 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Adrenal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Adrenal mass (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dependence on respirator (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Life support (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mental status changes (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Renal haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **1864** | click or scan<br>EU-EC-10011653124 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **1865** | click or scan<br>EU-EC-10011652960 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **1866** | click or scan<br>EU-EC-10011652912 | | 2022-02-18 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **1867** | click or scan<br>EU-EC-10011652858 | | 2022-02-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1868 | click or scan EU-EC-10011652745 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1869 | click or scan EU-EC-10011652741 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1870 | click or scan EU-EC-10011652699 | | 2022-02-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Limb deformity (n/a - Unknown - Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1871 | click or scan EU-EC-10011652688 | | 2022-02-18 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Unknown - ), Syncope (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1872 | click or scan EU-EC-10011652490 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1873 | click or scan EU-EC-10011652377 | | 2022-02-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 1874 | click or scan EU-EC-10011652227 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1875 | click or scan EU-EC-10011652158 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1876 | click or scan EU-EC-10011652136 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Aspiration (n/a - Unknown - ), Condition aggravated (8d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1877 | click or scan EU-EC-10011651673 | | 2022-02-18 | Healthcare Professional | EEA | 18-64 Years | Female | Stillbirth (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [LABETALOL HYDROCHLORIDE] (S - Hypertension - n/a - [n/a - 200mg - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1878 | click or scan EU-EC-10011651597 | | 2022-02-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**), Obstructive airways disorder (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1879 | click or scan EU-EC-10011651487 | | 2022-02-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1880 | click or scan EU-EC-10011651147 | | 2022-02-18 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arthralgia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1881 | click or scan EU-EC-10011651082 | | 2022-02-18 | Non Healthcare Professional | EEA | 18-64 Years | Female | Toxicity to various agents (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 1882 | click or scan EU-EC-10011651014 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anosmia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1883 | click or scan EU-EC-10011650391 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Female | Atrioventricular block complete (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1884 | click or scan EU-EC-10011650349 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1885 | click or scan EU-EC-10011650339 | | 2022-02-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1886 | click or scan EU-EC-10011650332 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1887 | click or scan EU-EC-10011650325 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Unknown - ), Disease recurrence (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1888 | click or scan EU-EC-10011650312 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Disease recurrence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - ), Pallor (n/a - Unknown - ), Purpura (n/a - Unknown - ), Rash erythematous (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1889 | click or scan EU-EC-10011650223 | | 2022-02-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1890 | click or scan EU-EC-10011650142 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysuria (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1891 | click or scan EU-EC-10011650091 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1892 | click or scan EU-EC-10011650091 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1893 | click or scan EU-EC-10011649951 | | 2022-02-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Unknown - Life Threatening), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Unknown - Life Threatening), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Life Threatening), Migraine (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1894 | click or scan EU-EC-10011649734 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1895 | click or scan EU-EC-10011649548 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1896 | click or scan EU-EC-10011649315 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1897 | click or scan EU-EC-10011648727 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), COVID-19 immunisation (n/a - Unknown - ), Cardiac failure (14d - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Staphylococcal sepsis (14d - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1898 | click or scan EU-EC-10011648610 | | 2022-02-18 | Non Healthcare Professional | EEA | Not Specified | Male | Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1899 | click or scan EU-EC-10011648610 | | 2022-02-18 | Non Healthcare Professional | EEA | Not Specified | Male | Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1900 | click or scan EU-EC-10011648610 | | 2022-02-18 | Non Healthcare Professional | EEA | Not Specified | Male | Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1901 | click or scan EU-EC-10011648568 | | 2022-02-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Gait inability (n/a - Fatal - **Results in Death**), Urinary retention (0d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1902 | click or scan EU-EC-10011648553 | | 2022-02-18 | Healthcare Professional | EEA | Not Specified | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1903 | click or scan EU-EC-10011648365 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pericardial haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1904 | click or scan EU-EC-10011648360 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic stroke (2d - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 1905 | click or scan EU-EC-10011648358 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Tuberculosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1906 | click or scan EU-EC-10011648321 | | 2022-02-18 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1907 | click or scan EU-EC-10011648319 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1908 | click or scan EU-EC-10011648142 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (5min - Fatal - **Results in Death**), COVID-19 (5min - Fatal - **Results in Death**), Chronic kidney disease (5min - Fatal - **Results in Death**), Hypertension (5min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1909 | click or scan EU-EC-10011648114 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - Life Threatening), Respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 1910 | click or scan EU-EC-10011647932 | | 2022-02-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Dizziness - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Intermittent claudication - Not applicable - [n/a - 1 {DF} - n/a]) |
| 1911 | click or scan EU-EC-10011647723 | | 2022-02-18 | Healthcare Professional | EEA | More than 85 Years | Female | Oedema peripheral (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1912 | click or scan EU-EC-10011647721 | | 2022-02-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1913 | click or scan EU-EC-10011647566 | | 2022-02-18 | Healthcare Professional | EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1914 | click or scan EU-EC-10011647442 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1915 | click or scan EU-EC-10011647172 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **1916** | click or scan EU-EC-10011647083 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Transient ischaemic attack (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **1917** | click or scan EU-EC-10011646626 | | 2022-02-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **1918** | click or scan EU-EC-10011646612 | | 2022-02-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenopia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Unknown - ), Nerve injury (n/a - Unknown - ), Neurological symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Stress (n/a - Unknown - ), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **1919** | click or scan EU-EC-10011646499 | | 2022-02-18 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Metastases to abdominal cavity (n/a - Fatal - **Results in Death**), Metastases to lung (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **1920** | click or scan EU-EC-10011646416 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial necrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **1921** | click or scan EU-EC-10011646093 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **1922** | click or scan EU-EC-10011645939 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **1923** | click or scan EU-EC-10011645632 | | 2022-02-18 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **1924** | click or scan EU-EC-10011645607 | | 2022-02-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **1925** | click or scan EU-EC-10011645319 | | 2022-02-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hyperhidrosis (7d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1926 | click or scan EU-EC-10011645317 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic hepatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean arterial pressure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 1927 | click or scan EU-EC-10011645301 | | 2022-02-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1928 | click or scan EU-EC-10011645201 | | 2022-02-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1929 | click or scan EU-EC-10011645132 | | 2022-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1930 | click or scan EU-EC-10011644932 | | 2022-02-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1931 | click or scan EU-EC-10011644699 | | 2022-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Anuria (11d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (11d - Fatal - **Results in Death**), Septic shock (11d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |
| 1932 | click or scan EU-EC-10011644529 | | 2022-02-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pericarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 1933 | click or scan EU-EC-10011644501 | | 2022-02-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1934 | click or scan EU-EC-10011644471 | | 2022-02-18 | Non Healthcare Professional | EEA | 18-64 Years | Female | Headache (11d - Fatal - **Results in Death**), Hypertensive crisis (11d - Fatal - **Results in Death**), Vomiting (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 1935 | click or scan EU-EC-10011643179 | | 2022-02-17 | Healthcare Professional | EEA | More than 85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1936 | click or scan EU-EC-10011643166 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - n/a - More in ICSR]) |
| 1937 | click or scan EU-EC-10011643150 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 1938 | click or scan EU-EC-10011642490 | | 2022-02-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - ), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [B/PHUKET/3073/2013-LIKE STRAIN, A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186)] (S - n/a - Not applicable - [n/a - n/a - Unknown]) |
| 1939 | click or scan EU-EC-10011641737 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest discomfort (n/a - Not Recovered/Not Resolved - ), Chest pain (n/a - Not Recovered/Not Resolved - ), Circulatory collapse (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1940 | click or scan EU-EC-10011641731 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Status epilepticus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1941 | click or scan EU-EC-10011641724 | | 2022-02-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Splenic rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1942 | click or scan EU-EC-10011641551 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (7wk - Fatal - **Results in Death**), Malaise (7wk - Fatal - **Results in Death**), Pneumonia (7wk - Fatal - **Results in Death**), Pulmonary embolism (7wk - Fatal - **Results in Death**), Pyrexia (7wk - Fatal - **Results in Death**), Vertigo (7wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1943 | click or scan EU-EC-10011641471 | | 2022-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening), Neoplasm malignant (n/a - Not Recovered/Not Resolved - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1944 | click or scan EU-EC-10011641231 | | 2022-02-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Fall (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1945 | click or scan EU-EC-10011641045 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1946 | click or scan EU-EC-10011640983 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1947 | click or scan EU-EC-10011640961 | | 2022-02-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1948 | click or scan EU-EC-10011640960 | | 2022-02-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 1949 | click or scan EU-EC-10011640951 | | 2022-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphoma (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular - More in ICSR]) |
| 1950 | click or scan EU-EC-10011640876 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not Resolved - ), Syncope (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1951 | click or scan EU-EC-10011640803 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1952 | click or scan EU-EC-10011640801 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**), Blast cells (n/a - Not Recovered/Not Resolved - ), Haematoma (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1953 | click or scan EU-EC-10011640644 | | 2022-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 50ug - Intramuscular]) |
| 1954 | click or scan EU-EC-10011639923 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1955 | click or scan EU-EC-10011639868 | | 2022-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Head injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1956 | click or scan EU-EC-10011639801 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cholangitis acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 1957 | click or scan EU-EC-10011639800 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Dyspepsia (n/a - Not Recovered/Not Resolved - ), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - n/a]) |
| 1958 | click or scan EU-EC-10011639733 | | 2022-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [217d - 1 {DF} - Intramuscular]), [PREDNISONE] (S - Osteoarthritis - n/a - [n/a - 15mg - Oral]) |
| 1959 | click or scan EU-EC-10011639697 | | 2022-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiopulmonary failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 1960 | click or scan EU-EC-10011639667 | | 2022-02-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Tachycardia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 1961 | click or scan EU-EC-10011639562 | | 2022-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Rhinitis (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1962 | click or scan EU-EC-10011639042 | | 2022-02-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem haemorrhage (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1963 | click or scan EU-EC-10011638833 | | 2022-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Contusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Diarrhoea haemorrhagic (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypophagia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Skin haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Skin weeping (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Sticky skin (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1964 | click or scan EU-EC-10011638649 | | 2022-02-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1965 | click or scan EU-EC-10011637688 | | 2022-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Lung neoplasm malignant (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1966 | click or scan EU-EC-10011637688 | | 2022-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Lung neoplasm malignant (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 1967 | click or scan EU-EC-10011637657 | | 2022-02-17 | Healthcare Professional | EEA | 18-64 Years | Male | Brain contusion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1968 | click or scan EU-EC-10011637582 | | 2022-02-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 1969 | click or scan EU-EC-10011637125 | | 2022-02-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1970 | click or scan EU-EC-10011636561 | | 2022-02-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1971 | click or scan EU-EC-10011636481 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (21h - Fatal - **Results in Death**), Pneumonia (21h - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 1972 | click or scan EU-EC-10011636273 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 1973 | click or scan EU-EC-10011635838 | | 2022-02-17 | Non Healthcare Professional | EEA | Not Specified | Female | Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1974 | click or scan EU-EC-10011635279 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 1975 | click or scan EU-EC-10011634856 | | 2022-02-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1976 | click or scan EU-EC-10011634667 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (9d - Fatal - **Results in Death**), Coma scale abnormal (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - Other Medically Important Condition), Death (0d - Fatal - **Results in Death**), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Intraventricular haemorrhage (6d - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (0d - Fatal - **Results in Death**), Oxygen saturation abnormal (n/a - Unknown - Other Medically Important Condition), Pain in extremity (5d - Recovered/Resolved - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Ventricular drainage (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 1977 | click or scan EU-EC-10011634578 | | 2022-02-17 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 1978 | click or scan EU-EC-10011634089 | | 2022-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1979 | click or scan EU-EC-10011633887 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Female | Bradycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (21d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyschezia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hydrocephalus (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1980 | click or scan EU-EC-10011633577 | | 2022-02-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1981 | click or scan EU-EC-10011633455 | | 2022-02-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 1982 | click or scan EU-EC-10011633052 | | 2022-02-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1983 | click or scan EU-EC-10011632874 | | 2022-02-17 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1984 | click or scan EU-EC-10011632867 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1985 | click or scan EU-EC-10011632862 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1986 | click or scan EU-EC-10011632852 | | 2022-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 1987 | click or scan EU-EC-10011632628 | | 2022-02-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (4mo - Fatal - **Results in Death**), Chest pain (4mo - Fatal - **Results in Death**), Dyspnoea (4mo - Fatal - **Results in Death**), Pneumonia (4mo - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 1988 | click or scan EU-EC-10011632557 | | 2022-02-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden cardiac death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1989 | click or scan EU-EC-10011632476 | | 2022-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 1990 | click or scan EU-EC-10011631696 | | 2022-02-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 1991 | click or scan EU-EC-10011631510 | | 2022-02-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Feeling jittery (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 1992 | click or scan EU-EC-10011631487 | | 2022-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Myocardial infarction (0d - Fatal - **Results in Death**), Pulmonary artery thrombosis (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 1993 | click or scan EU-EC-10011631223 | | 2022-02-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Subcutaneous]) |
| 1994 | click or scan EU-EC-10011630520 | | 2022-02-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1995 | click or scan EU-EC-10011630373 | | 2022-02-16 | Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular dysfunction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine associated enhanced disease (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 1996 | click or scan EU-EC-10011629456 | | 2022-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - ), Dyspnoea exertional (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - ), Oedema (n/a - Unknown - ), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericarditis tuberculous (n/a - Unknown - Other Medically Important Condition), Weight increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 1997 | click or scan EU-EC-10011629070 | | 2022-02-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 1998 | click or scan EU-EC-10011627855 | | 2022-02-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Pulmonary embolism (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 1999 | click or scan EU-EC-10011627297 | | 2022-02-16 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (13d - Fatal - **Results in Death**), Coma (13d - Fatal - **Results in Death**), Ischaemic cerebral infarction (13d - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory failure (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2000 | click or scan EU-EC-10011626663 | | 2022-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [1d - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2001 | click or scan EU-EC-10011626663 | | 2022-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [1d - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2002 | click or scan EU-EC-10011626468 | | 2022-02-16 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**), Vaccination failure (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 2003 | click or scan EU-EC-10011626431 | | 2022-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (15d - Fatal - **Results in Death**), Vaccination failure (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [169d - 3{DF} - Intramuscular]) |
| 2004 | click or scan EU-EC-10011626407 | | 2022-02-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Atrioventricular block (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| 2005 | click or scan EU-EC-10011626394 | | 2022-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular]) |
| 2006 | click or scan EU-EC-10011626021 | | 2022-02-16 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2007 | click or scan EU-EC-10011625963 | | 2022-02-16 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2008 | click or scan EU-EC-10011625699 | | 2022-02-16 | Healthcare Professional | EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2009 | click or scan EU-EC-10011625690 | | 2022-02-16 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Capillary leak syndrome (n/a - Fatal - **Results in Death**, Life Threatening), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Life Threatening), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2010 | click or scan EU-EC-10011625669 | | 2022-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cytology abnormal (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Obstruction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tremor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2011 | click or scan EU-EC-10011625651 | | 2022-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood lactate dehydrogenase increased (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eosinophil count increased (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), VIDAZA [AZACITIDINE] (S - Chronic leukaemia in remission - Not applicable - [9d - n/a - Intravenous drip]) |
| 2012 | click or scan EU-EC-10011625647 | | 2022-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Overdose (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 2013 | click or scan EU-EC-10011625578 | | 2022-02-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2014 | click or scan EU-EC-10011624382 | | 2022-02-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Glioblastoma multiforme (6mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2015 | click or scan EU-EC-10011624201 | | 2022-02-16 | Healthcare Professional | EEA | 65-85 Years | Male | Central nervous system vasculitis (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Facial paresis (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2016 | click or scan EU-EC-10011623427 | | 2022-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - ), Pain in extremity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2017 | click or scan EU-EC-10011623083 | | 2022-02-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2018 | click or scan EU-EC-10011622990 | | 2022-02-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2019 | click or scan EU-EC-10011622369 | | 2022-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Quadriplegia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory paralysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2020 | click or scan EU-EC-10011622058 | | 2022-02-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2021 | click or scan EU-EC-10011621562 | | 2022-02-16 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2022 | click or scan EU-EC-10011621331 | | 2022-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2023 | click or scan EU-EC-10011620720 | | 2022-02-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2024 | click or scan EU-EC-10011620717 | | 2022-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2025 | click or scan EU-EC-10011620654 | | 2022-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2026 | click or scan EU-EC-10011620592 | | 2022-02-16 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 2027 | click or scan EU-EC-10011620554 | | 2022-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2028 | click or scan EU-EC-10011620076 | | 2022-02-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2029 | click or scan EU-EC-10011619822 | | 2022-02-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2030 | click or scan EU-EC-10011619616 | | 2022-02-16 | Healthcare Professional | EEA | 65-85 Years | Male | Coronary artery occlusion (0d - Fatal - **Results in Death**), Immunisation (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2031 | click or scan EU-EC-10011619310 | | 2022-02-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - ), Discomfort (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2032 | click or scan EU-EC-10011618978 | | 2022-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arterial thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flank pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematuria (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nephrolithiasis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oral contusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral ischaemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyelonephritis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2033 | click or scan EU-EC-10011618960 | | 2022-02-16 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - Unknown]) |
| 2034 | click or scan EU-EC-10011618880 | | 2022-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2035 | click or scan EU-EC-10011618211 | | 2022-02-16 | Healthcare Professional | EEA | 65-85 Years | Male | Infarction (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 2036 | click or scan EU-EC-10011618086 | | 2022-02-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2037 | click or scan EU-EC-10011618080 | | 2022-02-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Migraine (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - n/a]) |
| 2038 | click or scan EU-EC-10011617898 | | 2022-02-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abdominal distension (220d - Fatal - **Results in Death**), Abdominal pain (220d - Fatal - **Results in Death**), Ascites (220d - Fatal - **Results in Death**), Fatigue (220d - Fatal - **Results in Death**), Pleural effusion (220d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2039 | click or scan EU-EC-10011617882 | | 2022-02-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2040 | click or scan EU-EC-10011617851 | | 2022-02-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Intestinal infarction (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2041 | click or scan EU-EC-10011617411 | | 2022-02-15 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Haemorrhage foetal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 2042 | click or scan EU-EC-10011616874 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Female | Constipation (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia staphylococcal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1 {DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2043 | click or scan EU-EC-10011616494 | | 2022-02-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Renal vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2044 | click or scan EU-EC-10011615594 | | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ophthalmic herpes zoster (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2045 | click or scan EU-EC-10011615576 | | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal loss of weight (n/a - Unknown - Other Medically Important Condition), Dyspepsia (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2046 | click or scan EU-EC-10011615563 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2047 | click or scan EU-EC-10011615563 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2048 | click or scan EU-EC-10011615215 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (0d - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5 {DF} - Intramuscular]) |
| 2049 | click or scan EU-EC-10011615086 | | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Respiratory rate decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2050 | click or scan EU-EC-10011615005 | | 2022-02-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2051 | click or scan EU-EC-10011614973 | | 2022-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2052 | click or scan EU-EC-10011613849 | | 2022-02-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Rash macular (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2053 | click or scan EU-EC-10011613690 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2054 | click or scan EU-EC-10011613638 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [82d - 2 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2055** | click or scan EU-EC-10011613636 | | 2022-02-15 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| **2056** | click or scan EU-EC-10011613098 | | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Splenitis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2057** | click or scan EU-EC-10011613077 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| **2058** | click or scan EU-EC-10011612826 | | 2022-02-15 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **2059** | click or scan EU-EC-10011612643 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **2060** | click or scan EU-EC-10011612501 | | 2022-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2061** | click or scan EU-EC-10011612501 | | 2022-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2062 | click or scan EU-EC-10011612134 |  | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchitis bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Dyspnoea (5wk - Unknown - Caused/Prolonged Hospitalisation), Endotracheal intubation (5wk - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertensive crisis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Intensive care (5wk - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - ), Oral herpes (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Other Medically Important Condition), Quadriparesis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Radiculopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Staphylococcal infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Tracheobronchitis bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation), Tracheostomy malfunction (5wk - Unknown - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2063 | click or scan EU-EC-10011611762 |  | 2022-02-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Recovering/Resolving - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Recovering/Resolving - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Pericardial effusion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovering/Resolving - ), Suspected COVID-19 (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2064 | click or scan EU-EC-10011611735 |  | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2065 | click or scan EU-EC-10011611705 |  | 2022-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2066 | click or scan EU-EC-10011611254 |  | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2067 | click or scan EU-EC-10011611237 |  | 2022-02-15 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wound sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2068 | click or scan EU-EC-10011611066 |  | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2069 | click or scan EU-EC-10011610501 | | 2022-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Apathy (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Communication disorder (n/a - Unknown - Other Medically Important Condition), Disorientation (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2070 | click or scan EU-EC-10011610132 | | 2022-02-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (10d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (10d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2071 | click or scan EU-EC-10011609195 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2072 | click or scan EU-EC-10011609127 | | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2073 | click or scan EU-EC-10011609110 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2074 | click or scan EU-EC-10011609090 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2075 | click or scan EU-EC-10011609026 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Insomnia (n/a - Unknown - ), Vaccination site hypoaesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2076 | click or scan EU-EC-10011608989 | | 2022-02-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asphyxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Urinary retention (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2077 | click or scan EU-EC-10011608751 | | 2022-02-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - ), Rhinitis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2078 | click or scan EU-EC-10011608750 | | 2022-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (4d - Fatal - **Results in Death**), Myelodysplastic syndrome (4d - Fatal - **Results in Death**), Pancytopenia (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2079 | click or scan EU-EC-10011608749 | | 2022-02-15 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2080 | click or scan EU-EC-10011608502 | | 2022-02-15 | Healthcare Professional | EEA | 18-64 Years | Male | Brain death (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain oedema (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2081 | click or scan EU-EC-10011608339 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2082 | click or scan EU-EC-10011608193 | | 2022-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Atelectasis (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Breath sounds abnormal (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Increased upper airway secretion (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 2083 | click or scan EU-EC-10011608168 | | 2022-02-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2084 | click or scan EU-EC-10011608109 | | 2022-02-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2085 | click or scan EU-EC-10011607966 | | 2022-02-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Balance disorder (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Dementia (n/a - Fatal - **Results in Death**), Emotional distress (n/a - Fatal - **Results in Death**), Erysipelas (n/a - Fatal - **Results in Death**), Eyelid ptosis (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Fear (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 2086 | click or scan EU-EC-10011607875 | | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Female | Choking (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Secretion discharge (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 2087 | click or scan EU-EC-10011607770 | | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2088 | click or scan EU-EC-10011607689 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2089 | click or scan EU-EC-10011607636 | | 2022-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2090 | click or scan EU-EC-10011607636 | | 2022-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2091 | click or scan EU-EC-10011607604 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Intramuscular]) |
| 2092 | click or scan EU-EC-10011607603 | | 2022-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2093 | click or scan EU-EC-10011607534 | | 2022-02-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal incarcerated hernia (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [85d - n/a - Intramuscular]) |
| 2094 | click or scan EU-EC-10011607331 | | 2022-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2095 | click or scan EU-EC-10011606761 | | 2022-02-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2096 | click or scan EU-EC-10011606618 | | 2022-02-15 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (9d - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2097 | click or scan EU-EC-10011606611 |  | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**), Embolic stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injection site pain (2d - Recovered/Resolved - ), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2098 | click or scan EU-EC-10011606405 |  | 2022-02-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**), Respiratory fatigue (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2099 | click or scan EU-EC-10011606384 |  | 2022-02-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abscess (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 2100 | click or scan EU-EC-10011606275 |  | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | Septic shock (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2101 | click or scan EU-EC-10011606259 |  | 2022-02-15 | Healthcare Professional | EEA | 65-85 Years | Female | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2102 | click or scan EU-EC-10011606230 |  | 2022-02-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Injection site reaction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2103 | click or scan EU-EC-10011605420 |  | 2022-02-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysgeusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic lesion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Non-Hodgkin's lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic lesion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tooth infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2104 | click or scan EU-EC-10011604582 |  | 2022-02-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Intramuscular]) |
| 2105 | click or scan EU-EC-10011604549 |  | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2106 | click or scan EU-EC-10011604272 |  | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2107 | click or scan EU-EC-10011604219 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2108 | click or scan EU-EC-10011604197 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2109 | click or scan EU-EC-10011604136 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Altered state of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2110 | click or scan EU-EC-10011604134 | | 2022-02-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2111 | click or scan EU-EC-10011604129 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2112 | click or scan EU-EC-10011604124 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 2113 | click or scan EU-EC-10011604110 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Abdominal pain upper (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2114 | click or scan EU-EC-10011604073 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2115 | click or scan EU-EC-10011603993 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 2116 | click or scan EU-EC-10011603946 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2117 | click or scan EU-EC-10011603906 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2118 | click or scan EU-EC-10011603868 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2119 | click or scan EU-EC-10011603837 | | 2022-02-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bradycardia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2120 | click or scan EU-EC-10011603833 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2121 | click or scan EU-EC-10011603799 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2122 | click or scan EU-EC-10011603595 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Unknown]) |
| 2123 | click or scan EU-EC-10011603226 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2124 | click or scan EU-EC-10011603106 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**), Hypertension (n/a - Unknown - ), Vaccination site discomfort (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2125 | click or scan EU-EC-10011603084 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Alanine aminotransferase increased (n/a - Unknown - ), Aspartate aminotransferase increased (n/a - Unknown - ), Blood bicarbonate decreased (n/a - Unknown - ), Blood creatine phosphokinase MB increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - ), Blood lactic acid increased (n/a - Unknown - ), Blood pH decreased (n/a - Unknown - ), Blood phosphorus increased (n/a - Unknown - ), Blood thyroid stimulating hormone increased (n/a - Unknown - ), Blood uric acid increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Gamma-glutamyltransferase increased (n/a - Unknown - ), Glycosylated haemoglobin increased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Lymphocyte count increased (n/a - Unknown - ), Lymphocyte percentage increased (n/a - Unknown - ), Metamyelocyte percentage increased (n/a - Unknown - ), Mydriasis (n/a - Unknown - ), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Other Medically Important Condition), Neutrophil percentage decreased (n/a - Unknown - ), Nutritional assessment (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), PCO2 increased (n/a - Unknown - ), PO2 decreased (n/a - Unknown - ), Protein total decreased (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Red blood cell count decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2126 | click or scan EU-EC-10011602864 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 2127 | click or scan EU-EC-10011602835 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cold sweat (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2128 | click or scan EU-EC-10011602833 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2129 | click or scan EU-EC-10011602832 | | 2022-02-14 | Non Healthcare Professional | EEA | Not Specified | Male | Neuritis (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2130 | click or scan EU-EC-10011602830 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2131 | click or scan EU-EC-10011602779 | | 2022-02-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2132 | click or scan EU-EC-10011602767 | | 2022-02-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2133 | click or scan EU-EC-10011602764 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2134 | click or scan EU-EC-10011602580 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2135 | click or scan EU-EC-10011602580 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2136 | click or scan EU-EC-10011602274 | | 2022-02-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiovascular disorder (n/a - Unknown - ), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2137 | click or scan EU-EC-10011602264 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 antibody test positive (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2138 | click or scan EU-EC-10011602264 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 antibody test positive (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2139 | click or scan EU-EC-10011601571 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Intestinal infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1min - 1 {DF} - Intramuscular]) |
| 2140 | click or scan EU-EC-10011601378 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2141 | click or scan EU-EC-10011601366 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2142 | click or scan EU-EC-10011601323 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 2143 | click or scan EU-EC-10011601293 | | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [268d - 1 {DF} - Intramuscular]) |
| 2144 | click or scan EU-EC-10011601292 | | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |
| 2145 | click or scan EU-EC-10011601270 | | 2022-02-14 | Healthcare Professional | EEA | Not Specified | Female | Renal aplasia (10d - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [72d - 2 {DF} - Transplacental]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2146 | click or scan EU-EC-10011601267 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 2147 | click or scan EU-EC-10011600903 | | 2022-02-14 | Healthcare Professional | EEA | Not Specified | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), SHINGRIX [RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E, STIMULON, MONOPHOSPHORYL LIPID A] (S - Immunisation - n/a - [n/a - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2148 | click or scan EU-EC-10011600727 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Restlessness (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2149 | click or scan EU-EC-10011600725 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2150 | click or scan EU-EC-10011600720 | | 2022-02-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2151 | click or scan EU-EC-10011600718 | | 2022-02-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2152 | click or scan EU-EC-10011600715 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2153 | click or scan EU-EC-10011600709 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - ), Mouth haemorrhage (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2154 | click or scan<br>EU-EC-10011600708 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2155 | click or scan<br>EU-EC-10011600706 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abnormal loss of weight (n/a - Not Recovered/Not Resolved - ), Cardiac discomfort (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Epistaxis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), [B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **2156** | click or scan EU-EC-10011600705 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac discomfort (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Influenza (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **2157** | click or scan EU-EC-10011600641 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection viral (n/a - Unknown - Other Medically Important Condition), Pneumonia bacterial (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Right ventricular systolic pressure increased (n/a - Fatal - **Results in Death**), Ventricular hypertrophy (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2158** | click or scan EU-EC-10011600614 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| **2159** | click or scan EU-EC-10011600605 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Headache (n/a - Unknown - ), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2160** | click or scan EU-EC-10011600095 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| **2161** | click or scan EU-EC-10011599538 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Anaemia (n/a - Unknown - ), Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fall (n/a - Unknown - ), Haemorrhagic diathesis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Palpitations (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Subdural haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2162 | click or scan EU-EC-10011599524 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Respiratory disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2163 | click or scan EU-EC-10011599219 | | 2022-02-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2164 | click or scan EU-EC-10011598898 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2165 | click or scan EU-EC-10011598869 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2166 | click or scan EU-EC-10011598866 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2167 | click or scan EU-EC-10011598796 | | 2022-02-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (48d - Fatal - **Results in Death**), Clinical death (31d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Decreased appetite (48d - Fatal - **Results in Death**), Gait disturbance (48d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2168 | click or scan EU-EC-10011598442 | | 2022-02-14 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Hypoplastic left heart syndrome (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2169 | click or scan EU-EC-10011598340 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acetabulum fracture (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Fat embolism (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Migraine (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Urticaria (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 2170 | click or scan EU-EC-10011598328 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [2d - n/a - Intramuscular]) |
| 2171 | click or scan EU-EC-10011598243 | | 2022-02-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac hypertrophy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2172 | click or scan EU-EC-10011598179 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hepatic cirrhosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2173 | click or scan EU-EC-10011598077 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2174 | click or scan EU-EC-10011598032 | | 2022-02-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pharyngeal oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 2175 | click or scan EU-EC-10011598026 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Female | Coronary artery disease (n/a - Fatal - **Results in Death**), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 2176 | click or scan EU-EC-10011597789 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 2177 | click or scan EU-EC-10011597645 | | 2022-02-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2178 | click or scan EU-EC-10011597369 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Female | Thrombocytopenia (4mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic microangiopathy (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2179 | click or scan EU-EC-10011597304 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (4mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2180 | click or scan EU-EC-10011597293 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2181 | click or scan EU-EC-10011597237 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Female | Death (0d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2182 | click or scan EU-EC-10011596906 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Female | Dysphagia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Inflammatory marker increased (n/a - Fatal - **Results in Death**), Muscle twitching (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 2183 | click or scan EU-EC-10011596696 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2184 | click or scan EU-EC-10011596186 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dysphagia (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Musculoskeletal disorder (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2185 | click or scan EU-EC-10011596150 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Status epilepticus (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Subcutaneous]) |
| 2186 | click or scan EU-EC-10011596050 | | 2022-02-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), XARELTO 20 MG FILM-COATED TABLETS [RIVAROXABAN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]) |
| 2187 | click or scan EU-EC-10011595662 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2188 | click or scan EU-EC-10011595495 | | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2189 | click or scan EU-EC-10011595327 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Putamen haemorrhage (n/a - Fatal - **Results in Death**), Thalamus haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2190 | click or scan EU-EC-10011595182 | | 2022-02-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2191 | click or scan EU-EC-10011594889 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2192 | click or scan EU-EC-10011594746 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (8d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2193 | click or scan EU-EC-10011594667 | | 2022-02-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2194 | click or scan EU-EC-10011594665 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2195 | click or scan EU-EC-10011594622 | | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2196 | click or scan EU-EC-10011594389 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | Demyelinating polyneuropathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2197 | click or scan EU-EC-10011594379 | | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2198 | click or scan EU-EC-10011594376 | | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2199 | click or scan EU-EC-10011594368 | | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2200 | click or scan EU-EC-10011594361 | | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Male | Malaise (2d - Fatal - **Results in Death**), Nausea (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]) |
| 2201 | click or scan EU-EC-10011594354 | | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2202 | click or scan EU-EC-10011594339 | | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | Hypersensitivity myocarditis (5mo - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (5mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2203 | click or scan EU-EC-10011594321 |  | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2204 | click or scan EU-EC-10011594280 |  | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (18d - Fatal - **Results in Death**), Cerebral infarction (18d - Fatal - **Results in Death**), Cerebrovascular accident (4d - Fatal - **Results in Death**), Dizziness (18d - Fatal - **Results in Death**), Drug ineffective (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (I - Immunisation - n/a - [n/a - n/a - Intramuscular]), ELIQUIS [APIXABAN] (I - Atrial fibrillation - n/a - [n/a - n/a - n/a]) |
| 2205 | click or scan EU-EC-10011594278 |  | 2022-02-14 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (7d - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (7d - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (7d - Fatal - **Results in Death**, Other Medically Important Condition), Physical deconditioning (7d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (7d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2206 | click or scan EU-EC-10011594261 |  | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2207 | click or scan EU-EC-10011594225 |  | 2022-02-14 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2208 | click or scan EU-EC-10011594195 |  | 2022-02-14 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic stenosis (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2209 | click or scan EU-EC-10011594001 |  | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (3d - Fatal - **Results in Death**), Chills (3d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Pain (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2210 | click or scan EU-EC-10011593891 |  | 2022-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Huntington's disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypophagia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2211 | click or scan EU-EC-10011593599 |  | 2022-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (23min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2212 | click or scan EU-EC-10011591644 |  | 2022-02-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2213 | click or scan EU-EC-10011591585 | | 2022-02-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2214 | click or scan EU-EC-10011590804 | | 2022-02-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain lower (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Rales (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2215 | click or scan EU-EC-10011590803 | | 2022-02-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**), Monoparesis (n/a - Fatal - **Results in Death**), Odynophagia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 2216 | click or scan EU-EC-10011590193 | | 2022-02-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2217 | click or scan EU-EC-10011590093 | | 2022-02-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Hepatic cirrhosis (n/a - Fatal - **Results in Death**), Obesity (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2218 | click or scan EU-EC-10011590007 | | 2022-02-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2219 | click or scan EU-EC-10011588357 | | 2022-02-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2220 | click or scan EU-EC-10011588121 | | 2022-02-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2221 | click or scan EU-EC-10011588078 | | 2022-02-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2222 | click or scan EU-EC-10011586716 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2223 | click or scan EU-EC-10011586237 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2224** | click or scan EU-EC-10011585767 | | 2022-02-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (0d - Fatal - **Results in Death**, Other Medically Important Condition), Brain oedema (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Heart rate increased (n/a - Not Recovered/Not Resolved - ), Left ventricular dysfunction (n/a - Fatal - **Results in Death**), Myalgia (n/a - Not Recovered/Not Resolved - ), Myocarditis (0d - Fatal - **Results in Death**, Other Medically Important Condition), Oropharyngeal pain (n/a - Recovered/Resolved - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pyrexia (0d - Recovered/Resolved - ), Splenomegaly (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition), Vascular calcification (n/a - Unknown - Other Medically Important Condition), Vasculitis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Influenza immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **2225** | click or scan EU-EC-10011585608 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Colitis ischaemic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lactic acidosis (n/a - Unknown - Other Medically Important Condition), Renal infarct (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock haemorrhagic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Systemic candida (n/a - Unknown - Other Medically Important Condition), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **2226** | click or scan EU-EC-10011585590 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse reaction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Intramuscular]) |
| **2227** | click or scan EU-EC-10011585271 | | 2022-02-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2228** | click or scan EU-EC-10011585255 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **2229** | click or scan EU-EC-10011584999 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2230** | click or scan EU-EC-10011584908 | | 2022-02-11 | Non Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2231 | click or scan EU-EC-10011584366 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain stem syndrome (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Communication disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Device related infection (n/a - Unknown - Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysuria (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal sounds abnormal (n/a - Unknown - ), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hiccups (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperthermia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Unknown - ), Hypotension (n/a - Unknown - ), Ileus paralytic (n/a - Unknown - Other Medically Important Condition), Immune-mediated encephalitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Unknown - ), Logorrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - ), Pain (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pollakiuria (n/a - Unknown - Caused/Prolonged Hospitalisation), Prostatitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ), Sepsis (n/a - Unknown - Other Medically Important Condition), Sinus tachycardia (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Urinary retention (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2232 | click or scan EU-EC-10011583774 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2233 | click or scan EU-EC-10011583274 | | 2022-02-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2234 | click or scan EU-EC-10011582676 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2235 | click or scan EU-EC-10011582665 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2236 | click or scan EU-EC-10011582520 | | 2022-02-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2237 | click or scan EU-EC-10011582419 | | 2022-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Capillary leak syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased activity (n/a - Unknown - Caused/Prolonged Hospitalisation), Hiccups (n/a - Unknown - ), Hypercapnia (n/a - Unknown - ), Immune-mediated adverse reaction (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Organising pneumonia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pseudomonas test positive (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Staphylococcus test positive (n/a - Unknown - ), Urine output decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2238 | click or scan EU-EC-10011581543 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrioventricular block (8d - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 2239 | click or scan EU-EC-10011581113 | | 2022-02-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2240 | click or scan EU-EC-10011580908 | | 2022-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2241 | click or scan EU-EC-10011580890 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), XARELTO [RIVAROXABAN] (S - Thrombosis prophylaxis - Not applicable - [n/a - 20mg - Oral]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Thrombosis prophylaxis - Not applicable - [n/a - 75mg - Oral]) |
| 2242 | click or scan EU-EC-10011580886 | | 2022-02-11 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2243 | click or scan EU-EC-10011580857 | | 2022-02-11 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2244 | click or scan EU-EC-10011580822 | | 2022-02-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2245 | click or scan EU-EC-10011580734 | | 2022-02-11 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2246 | click or scan EU-EC-10011580569 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .25mL - Intramuscular]) |
| 2247 | click or scan EU-EC-10011580530 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Hypoxia (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2248 | click or scan EU-EC-10011579987 | | 2022-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2249 | click or scan EU-EC-10011579696 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2250 | click or scan EU-EC-10011579556 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricle rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2251 | click or scan EU-EC-10011579336 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 2252 | click or scan EU-EC-10011579333 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2253 | click or scan EU-EC-10011579271 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Meningitis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2254 | click or scan EU-EC-10011579002 | | 2022-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic valve incompetence (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Cholecystitis acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cholelithiasis (n/a - Unknown - ), Gallbladder hypofunction (n/a - Unknown - Other Medically Important Condition), Heart rate increased (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Oral candidiasis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - ), Rash (790min - Recovered/Resolved - ), Renal disorder (n/a - Unknown - ), Sepsis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2255 | click or scan EU-EC-10011578985 | | 2022-02-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**), Essential hypertension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2256 | click or scan EU-EC-10011578917 | | 2022-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2257 | click or scan EU-EC-10011578431 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (30min - Fatal - **Results in Death**), Dyspnoea (30min - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2258 | click or scan EU-EC-10011578230 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2259 | click or scan EU-EC-10011578228 | | 2022-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Joint dislocation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2260 | click or scan EU-EC-10011578216 | | 2022-02-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pericarditis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2261 | click or scan EU-EC-10011578212 | | 2022-02-11 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2262 | click or scan EU-EC-10011578106 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2263 | click or scan EU-EC-10011577854 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Respiratory distress (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2264 | click or scan EU-EC-10011577801 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Seizure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2265 | click or scan EU-EC-10011577797 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (3d - Fatal - **Results in Death**), COVID-19 (2d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Pain in extremity (3d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2266 | click or scan EU-EC-10011576990 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2267** | click or scan EU-EC-10011576985 | | 2022-02-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pancreatitis (89d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **2268** | click or scan EU-EC-10011576749 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sensory processing disorder (1d - Recovered/Resolved - Other Medically Important Condition), Sluggishness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2269** | click or scan EU-EC-10011576749 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sensory processing disorder (1d - Recovered/Resolved - Other Medically Important Condition), Sluggishness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2270** | click or scan EU-EC-10011576654 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **2271** | click or scan EU-EC-10011576576 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2272** | click or scan EU-EC-10011576286 | | 2022-02-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Delirium (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Device related sepsis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastroenteritis viral (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersomnia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| **2273** | click or scan EU-EC-10011576255 | | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2274** | click or scan EU-EC-10011576134 | | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2275 | click or scan EU-EC-10011575614 |  | 2022-02-11 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**), Sudden hearing loss (n/a - Not Recovered/Not Resolved - ), Vestibular disorder (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Influenza immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2276 | click or scan EU-EC-10011575493 |  | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyschezia (n/a - Fatal - **Results in Death**), Dysuria (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2277 | click or scan EU-EC-10011575396 |  | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2278 | click or scan EU-EC-10011575302 |  | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2279 | click or scan EU-EC-10011575201 |  | 2022-02-11 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2280 | click or scan EU-EC-10011574643 |  | 2022-02-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 2281 | click or scan EU-EC-10011574485 |  | 2022-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2282 | click or scan EU-EC-10011574075 |  | 2022-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 2283 | click or scan EU-EC-10011574073 |  | 2022-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rhonchi (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2284** | click or scan EU-EC-10011574004 | | 2022-02-11 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure acute (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **2285** | click or scan EU-EC-10011572858 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Female | Dysarthria (2d - Fatal - **Results in Death**), Hemiplegia (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - .25mL - n/a]), INHIXA 10,000 IU (100 MG)/1 ML SOLUTION FOR INJECTION [ENOXAPARIN SODIUM] (S - Thrombophlebitis - Not applicable - [n/a - 6000k[iU] - Subcutaneous]) |
| **2286** | click or scan EU-EC-10011572772 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Respiratory arrest (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .25mL - Intramuscular]) |
| **2287** | click or scan EU-EC-10011572559 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Fibrin D dimer increased (26d - Fatal - **Results in Death**), Splenic haemorrhage (26d - Fatal - **Results in Death**), Splenic rupture (26d - Fatal - **Results in Death**), Thrombocytopenia (26d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2288** | click or scan EU-EC-10011572499 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Female | Ventricular fibrillation (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2289** | click or scan EU-EC-10011572485 | | 2022-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Chills (1d - Fatal - **Results in Death**), Cyanosis (1d - Fatal - **Results in Death**), Hyperpyrexia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2290** | click or scan EU-EC-10011572368 | | 2022-02-11 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Metabolic acidosis (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Shock (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]) |
| **2291** | click or scan EU-EC-10011571971 | | 2022-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **2292** | click or scan EU-EC-10011571070 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2293** | click or scan EU-EC-10011570838 | | 2022-02-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Unknown - ), Cyanosis (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2294 | click or scan EU-EC-10011570642 | | 2022-02-10 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Dyskinesia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2295 | click or scan EU-EC-10011570542 | | 2022-02-10 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2296 | click or scan EU-EC-10011570052 | | 2022-02-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Eye disorder (n/a - Unknown - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2297 | click or scan EU-EC-10011569594 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Burkitt's lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2298 | click or scan EU-EC-10011569510 | | 2022-02-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Headache (n/a - Unknown - ), Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2299 | click or scan EU-EC-10011569478 | | 2022-02-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2300 | click or scan EU-EC-10011569050 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2301 | click or scan EU-EC-10011568699 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 2302 | click or scan EU-EC-10011568629 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]), VENCLYXTO [VENETOCLAX] (S - Chronic lymphocytic leukaemia - Drug withdrawn - [n/a - n/a - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2303 | click or scan EU-EC-10011568629 |  | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]), VENCLYXTO [VENETOCLAX] (S - Chronic lymphocytic leukaemia - Drug withdrawn - [n/a - n/a - Oral]) |
| 2304 | click or scan EU-EC-10011568197 |  | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (5d - Recovered/Resolved - ), Respiratory disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2305 | click or scan EU-EC-10011567698 |  | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2306 | click or scan EU-EC-10011567698 |  | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2307 | click or scan EU-EC-10011567478 |  | 2022-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Blood loss anaemia (n/a - Unknown - Other Medically Important Condition), Cerebral artery thrombosis (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Infarction (n/a - Unknown - Other Medically Important Condition), Lacunar infarction (n/a - Unknown - Other Medically Important Condition), Normochromic normocytic anaemia (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Prostate cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2308 | click or scan EU-EC-10011566697 |  | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2309 | click or scan EU-EC-10011566635 |  | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 2310 | click or scan EU-EC-10011566502 |  | 2022-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2311 | click or scan EU-EC-10011566442 |  | 2022-02-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2312 | click or scan EU-EC-10011565994 | | 2022-02-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Disease recurrence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Eye disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Miller Fisher syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2313 | click or scan EU-EC-10011565946 | | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Appendix cancer (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2314 | click or scan EU-EC-10011565593 | | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2315 | click or scan EU-EC-10011565547 | | 2022-02-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2316 | click or scan EU-EC-10011565239 | | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2317 | click or scan EU-EC-10011565239 | | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2318 | click or scan EU-EC-10011565183 | | 2022-02-10 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2319 | click or scan EU-EC-10011564975 | | 2022-02-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Apnoea (n/a - Not Recovered/Not Resolved - Life Threatening), Arrhythmia (n/a - Not Recovered/Not Resolved - Life Threatening), COVID-19 immunisation (n/a - Unknown - ), Cardiac arrest (n/a - Not Recovered/Not Resolved - Life Threatening), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mydriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2320 | click or scan EU-EC-10011564825 | | 2022-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2321 | click or scan EU-EC-10011564556 | | 2022-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2322 | click or scan EU-EC-10011564502 | | 2022-02-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2323 | click or scan EU-EC-10011563632 | | 2022-02-10 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2324 | click or scan EU-EC-10011563613 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2325 | click or scan EU-EC-10011563533 | | 2022-02-10 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2326 | click or scan EU-EC-10011563437 | | 2022-02-10 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]), NOT AVAILABLE [MRNA 1273] (S - Immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 2327 | click or scan EU-EC-10011563089 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Thrombophlebitis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2328 | click or scan EU-EC-10011562884 | | 2022-02-10 | Healthcare Professional | EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Liver disorder (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Venous thrombosis limb (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 2329 | click or scan EU-EC-10011562882 | | 2022-02-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Cerebral thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Incoherent (n/a - Unknown - ), Joint swelling (n/a - Unknown - ), Neurological symptom (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 2330 | click or scan EU-EC-10011562350 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2331 | click or scan EU-EC-10011562338 |  | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2332 | click or scan EU-EC-10011562312 |  | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2333 | click or scan EU-EC-10011562282 |  | 2022-02-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (3d - Recovered/Resolved - ), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2334 | click or scan EU-EC-10011562127 |  | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic metabolic decompensation (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 2335 | click or scan EU-EC-10011562087 |  | 2022-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2336 | click or scan EU-EC-10011561906 |  | 2022-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2337 | click or scan EU-EC-10011561283 |  | 2022-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fall (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 2338 | click or scan EU-EC-10011561268 |  | 2022-02-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2339 | click or scan EU-EC-10011560915 |  | 2022-02-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Hypertension (n/a - Not Recovered/Not Resolved - ), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2340 | click or scan EU-EC-10011560805 |  | 2022-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2341 | click or scan EU-EC-10011560157 | | 2022-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Oropharyngeal discomfort (n/a - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2342 | click or scan EU-EC-10011559793 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2343 | click or scan EU-EC-10011559786 | | 2022-02-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Hypertension (2d - Fatal - **Results in Death**), Pain (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2344 | click or scan EU-EC-10011559723 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2345 | click or scan EU-EC-10011559668 | | 2022-02-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Soft tissue infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2346 | click or scan EU-EC-10011559655 | | 2022-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a]) |
| 2347 | click or scan EU-EC-10011559618 | | 2022-02-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Oedema peripheral (33d - Fatal - **Results in Death**), Petechiae (33d - Fatal - **Results in Death**), Thrombosis (33d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2348 | click or scan EU-EC-10011559615 | | 2022-02-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (72d - Fatal - **Results in Death**), Asthenia (72d - Fatal - **Results in Death**), Decreased appetite (72d - Fatal - **Results in Death**), Thrombocytopenia (72d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 2349 | click or scan EU-EC-10011559607 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (86d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2350 | click or scan EU-EC-10011559600 | | 2022-02-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (65d - Fatal - **Results in Death**), Deep vein thrombosis (65d - Fatal - **Results in Death**), Hyperpyrexia (65d - Fatal - **Results in Death**), Neuralgia (65d - Fatal - **Results in Death**), Pulmonary embolism (65d - Fatal - **Results in Death**), Sepsis (65d - Fatal - **Results in Death**), Urinary tract infection (65d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2351 | click or scan EU-EC-10011559596 | | 2022-02-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Fear (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2352 | click or scan EU-EC-10011559593 | | 2022-02-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain upper (13d - Fatal - **Results in Death**), Cardiac arrest (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 2353 | click or scan EU-EC-10011559583 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 2354 | click or scan EU-EC-10011559577 | | 2022-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 2355 | click or scan EU-EC-10011559530 | | 2022-02-10 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2356 | click or scan EU-EC-10011556692 | | 2022-02-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2357 | click or scan EU-EC-10011556669 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Unknown - Life Threatening), Cerebral haemorrhage (n/a - Unknown - Life Threatening), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Contusion (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening), Jugular vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening), Petechiae (n/a - Unknown - Life Threatening), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening), Pupil fixed (n/a - Unknown - Life Threatening), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening), Vena cava thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2358 | click or scan EU-EC-10011556525 | | 2022-02-09 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2359 | click or scan EU-EC-10011555427 | | 2022-02-09 | Non Healthcare Professional | EEA | Not Specified | Male | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - n/a]) |
| 2360 | click or scan EU-EC-10011555341 | | 2022-02-09 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2361 | click or scan EU-EC-10011554622 |  | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Enzyme level increased (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Hypertrophic cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (n/a - Unknown - ), Metabolic acidosis (n/a - Unknown - ), Mitral valve incompetence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral coldness (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2362 | click or scan EU-EC-10011554230 |  | 2022-02-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 2363 | click or scan EU-EC-10011553901 |  | 2022-02-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 2364 | click or scan EU-EC-10011553637 |  | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypertensive nephropathy (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 2365 | click or scan EU-EC-10011552854 |  | 2022-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 2366 | click or scan EU-EC-10011552811 |  | 2022-02-09 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 2367 | click or scan EU-EC-10011552790 |  | 2022-02-09 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| 2368 | click or scan EU-EC-10011552747 |  | 2022-02-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [84d - n/a - Intramuscular]) |
| 2369 | click or scan EU-EC-10011552747 |  | 2022-02-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [84d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2370 | click or scan EU-EC-10011552116 |  | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2371 | click or scan EU-EC-10011552116 |  | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2372 | click or scan EU-EC-10011552067 |  | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2373 | click or scan EU-EC-10011551852 |  | 2022-02-09 | Healthcare Professional | EEA | 18-64 Years | Male | Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2374 | click or scan EU-EC-10011551820 |  | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2375 | click or scan EU-EC-10011551818 |  | 2022-02-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2376 | click or scan EU-EC-10011551808 |  | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2377 | click or scan EU-EC-10011551666 |  | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Drowning (1d - Fatal - **Results in Death**, Other Medically Important Condition), Listless (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2378 | click or scan EU-EC-10011550977 |  | 2022-02-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Epistaxis (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2379 | click or scan EU-EC-10011550691 |  | 2022-02-09 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Spina bifida (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2380 | click or scan EU-EC-10011550411 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ascites (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic nephropathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperlipidaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nephropathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thyroid disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 2381 | click or scan EU-EC-10011550254 | | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung adenocarcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Metastasis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nasal cavity cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Visual impairment (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2382 | click or scan EU-EC-10011550221 | | 2022-02-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Generalised oedema (n/a - Fatal - **Results in Death**), Loss of personal independence in daily activities (n/a - Unknown - ), Mouth breathing (n/a - Unknown - ), Pleural effusion (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2383 | click or scan EU-EC-10011549593 | | 2022-02-09 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2384 | click or scan EU-EC-10011549538 | | 2022-02-09 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral infarction (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2385 | click or scan EU-EC-10011549393 | | 2022-02-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Not Recovered/Not Resolved - Life Threatening), Death (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2386 | click or scan EU-EC-10011549271 | | 2022-02-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Haemoptysis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2387 | click or scan EU-EC-10011548984 | | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2388 | click or scan EU-EC-10011548817 | | 2022-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 2389 | click or scan EU-EC-10011547930 | | 2022-02-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2390 | click or scan EU-EC-10011547857 | | 2022-02-09 | Non Healthcare Professional | EEA | Not Specified | Male | Arthralgia (n/a - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2391 | click or scan EU-EC-10011547856 | | 2022-02-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Cerebral thrombosis (2d - Fatal - **Results in Death**), Cerebrovascular accident (2d - Fatal - **Results in Death**), Chills (4d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Diarrhoea (4d - Fatal - **Results in Death**), Endocarditis (4d - Fatal - **Results in Death**), Fatigue (4d - Fatal - **Results in Death**), Headache (4d - Fatal - **Results in Death**), Immune-mediated adverse reaction (4d - Fatal - **Results in Death**), Malaise (4d - Fatal - **Results in Death**), Myalgia (4d - Fatal - **Results in Death**), Nausea (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**), Sepsis (4d - Fatal - **Results in Death**), Vomiting (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2392 | click or scan EU-EC-10011547366 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial ischaemia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 2393 | click or scan EU-EC-10011547146 | | 2022-02-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Immunisation reaction (n/a - Fatal - **Results in Death**), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2394 | click or scan EU-EC-10011546979 | | 2022-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 2395 | click or scan EU-EC-10011546955 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2396 | click or scan EU-EC-10011546886 | | 2022-02-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Embolic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2397 | click or scan EU-EC-10011546531 | | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 2398 | click or scan EU-EC-10011546456 | | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Factor XIII deficiency (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2399 | click or scan EU-EC-10011546393 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Intra-abdominal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 2400 | click or scan EU-EC-10011546388 | | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2401 | click or scan EU-EC-10011546265 | | 2022-02-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2402 | click or scan EU-EC-10011546264 | | 2022-02-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 2403 | click or scan EU-EC-10011545920 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Activated partial thromboplastin time prolonged (n/a - Unknown - Other Medically Important Condition), Haemorrhoids (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Spinal pain (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Thrombosis (11d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2404 | click or scan EU-EC-10011545906 | | 2022-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2405 | click or scan EU-EC-10011545841 | | 2022-02-09 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 2406 | click or scan EU-EC-10011545235 | | 2022-02-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haematochezia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Transient ischaemic attack (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2407** | click or scan<br>EU-EC-10011545116 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **2408** | click or scan<br>EU-EC-10011544914 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Anxiety (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Delirium (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage foetal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Heart rate increased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Heart sounds (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Limb discomfort (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Maternal exposure during breast feeding (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Musculoskeletal pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Off label use (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Panic attack (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Product use issue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiration abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rotator cuff syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tendonitis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2409 | click or scan EU-EC-10011544914 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Anxiety (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Delirium (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage foetal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Heart rate increased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Heart sounds (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Limb discomfort (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Maternal exposure during breast feeding (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Musculoskeletal pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Off label use (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Panic attack (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Product use issue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiration abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rotator cuff syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tendonitis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2410 | click or scan EU-EC-10011544673 | | 2022-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2411 | click or scan EU-EC-10011544233 | | 2022-02-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cough (54d - Fatal - **Results in Death**), Embolism (54d - Fatal - **Results in Death**), Myalgia (54d - Fatal - **Results in Death**), Pyrexia (54d - Fatal - **Results in Death**), Septic shock (54d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2412 | click or scan EU-EC-10011544195 | | 2022-02-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2413 | click or scan EU-EC-10011544152 | | 2022-02-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Biliary ischaemia (59d - Fatal - **Results in Death**), Cerebrovascular accident (59d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 2414 | click or scan EU-EC-10011544043 | | 2022-02-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2415 | click or scan EU-EC-10011543841 | | 2022-02-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Polymenorrhoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2416 | click or scan EU-EC-10011543672 | | 2022-02-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2417 | click or scan EU-EC-10011542780 | | 2022-02-08 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2418 | click or scan EU-EC-10011542779 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [67d - 1 {DF} - Intramuscular]) |
| 2419 | click or scan EU-EC-10011542452 | | 2022-02-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial flutter (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradykinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tearfulness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 2420 | click or scan EU-EC-10011542448 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Male | Atrial thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vena cava thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .25mL - Intramuscular]) |
| 2421 | click or scan EU-EC-10011542440 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Male | Bronchospasm (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 2422 | click or scan EU-EC-10011542415 | | 2022-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 2423 | click or scan EU-EC-10011541209 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2424 | click or scan EU-EC-10011541160 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Respiratory acidosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2425 | click or scan EU-EC-10011541158 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bacterial infection (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Propofol infusion syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2426 | click or scan EU-EC-10011540908 | | 2022-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 2427 | click or scan EU-EC-10011540862 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), VALSARTAN, SACUBITRIL [VALSARTAN, SACUBITRIL] (S - Cardiac failure - Unknown - [n/a - 2{DF} - Oral]) |
| 2428 | click or scan EU-EC-10011540842 | | 2022-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dementia Alzheimer's type (1d - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2429 | click or scan EU-EC-10011540818 | | 2022-02-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2430 | click or scan EU-EC-10011540444 | | 2022-02-08 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Limb discomfort (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Skin discolouration (n/a - Unknown - ), Sluggishness (n/a - Unknown - ), Vaccination site pruritus (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 2431 | click or scan EU-EC-10011540360 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening), Chills (n/a - Fatal - **Results in Death**, Life Threatening), Diplegia (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2432 | click or scan EU-EC-10011540156 | | 2022-02-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2433 | click or scan EU-EC-10011540153 | | 2022-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 2434 | click or scan EU-EC-10011540113 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Embolism arterial (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2435 | click or scan EU-EC-10011540108 | | 2022-02-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 2436 | click or scan EU-EC-10011540105 | | 2022-02-08 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2437 | click or scan EU-EC-10011539154 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2438 | click or scan EU-EC-10011539079 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2439 | click or scan EU-EC-10011539069 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2440 | click or scan EU-EC-10011539067 | | 2022-02-08 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2441 | click or scan EU-EC-10011539060 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (35d - Fatal - **Results in Death**), Vaccination failure (35d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1 {DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), GAZYVARO 1,000 MG CONCENTRATE FOR SOLUTION FOR INFUSION [OBINUTUZUMAB] (S - Non-Hodgkin's lymphoma - Not applicable - [288d - 1000mg - Oral]), REVLIMID [LENALIDOMIDE] (S - Non-Hodgkin's lymphoma - Not applicable - [37d - 20mg - Oral]), [CASIRIVIMAB, IMDEVIMAB] (S - COVID-19 prophylaxis - Not applicable - [1d - 600mg - Intravenous (not otherwise specified)]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2442 | click or scan EU-EC-10011539060 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (35d - Fatal - **Results in Death**), Vaccination failure (35d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1{DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), GAZYVARO 1,000 MG CONCENTRATE FOR SOLUTION FOR INFUSION [OBINUTUZUMAB] (S - Non-Hodgkin's lymphoma - Not applicable - [288d - 1000mg - Oral]), REVLIMID [LENALIDOMIDE] (S - Non-Hodgkin's lymphoma - Not applicable - [37d - 20mg - Oral]), [CASIRIVIMAB, IMDEVIMAB] (S - COVID-19 prophylaxis - Not applicable - [1d - 600mg - Intravenous (not otherwise specified)]) |
| 2443 | click or scan EU-EC-10011538997 | | 2022-02-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 2444 | click or scan EU-EC-10011538932 | | 2022-02-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2445 | click or scan EU-EC-10011538912 | | 2022-02-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 2446 | click or scan EU-EC-10011538783 | | 2022-02-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypoaesthesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Inappropriate schedule of product administration (n/a - Unknown - ), Shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site induration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2447 | click or scan EU-EC-10011538723 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2448 | click or scan EU-EC-10011538328 | | 2022-02-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Abdominal pain upper (n/a - Unknown - Disabling, Other Medically Important Condition), Abnormal loss of weight (n/a - Unknown - Disabling, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Hyporeflexia (n/a - Unknown - Disabling, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2449 | click or scan EU-EC-10011538315 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2450 | click or scan EU-EC-10011537658 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Head injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 2451 | click or scan EU-EC-10011537591 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Back pain (n/a - Unknown - Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous]) |
| 2452 | click or scan EU-EC-10011537582 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2453 | click or scan EU-EC-10011537573 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2454 | click or scan EU-EC-10011537274 | | 2022-02-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (4wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Back pain (2wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Back pain (4wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Constipation (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Diarrhoea (4wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Discoloured vomit (2wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Dysphagia (n/a - Unknown - Disabling, Other Medically Important Condition), Erythema (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Faeces discoloured (4wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Fatigue (4wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Gait inability (4wk - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition), Gait inability (n/a - Unknown - Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypotonia (n/a - Unknown - Disabling, Other Medically Important Condition), Language disorder (n/a - Unknown - Other Medically Important Condition), Vertigo (2wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Vertigo (4wk - Recovered/Resolved With Sequelae - Other Medically Important Condition), Vomiting (2wk - Recovered/Resolved With Sequelae - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 2455 | click or scan EU-EC-10011537202 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2456 | click or scan EU-EC-10011537178 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2457 | click or scan EU-EC-10011537144 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2458 | click or scan EU-EC-10011537102 | | 2022-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | C-reactive protein increased (n/a - Unknown - ), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myelitis transverse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nystagmus (n/a - Unknown - ), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Paraplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleocytosis (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2459 | click or scan EU-EC-10011537091 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2460 | click or scan EU-EC-10011536397 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Influenza like illness (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2461 | click or scan EU-EC-10011536353 | | 2022-02-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2462 | click or scan EU-EC-10011536335 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pericardial effusion (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2463 | click or scan EU-EC-10011536288 | | 2022-02-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Immune system disorder (10d - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2464 | click or scan EU-EC-10011536259 | | 2022-02-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2465 | click or scan EU-EC-10011536013 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2466 | click or scan EU-EC-10011535789 | | 2022-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2467 | click or scan EU-EC-10011535649 | | 2022-02-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2468 | click or scan EU-EC-10011535160 | | 2022-02-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - ), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Rash erythematous (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 2469 | click or scan EU-EC-10011534505 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2470 | click or scan EU-EC-10011534505 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2471 | click or scan EU-EC-10011534387 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2472 | click or scan EU-EC-10011534339 | | 2022-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2473 | click or scan EU-EC-10011534316 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2474 | click or scan EU-EC-10011534312 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2475 | click or scan EU-EC-10011534308 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2476 | click or scan EU-EC-10011534194 | | 2022-02-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 2477 | click or scan EU-EC-10011534178 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Platelet count increased (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 2478 | click or scan EU-EC-10011534160 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Female | Left ventricular hypertrophy (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2479 | click or scan EU-EC-10011533763 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2480 | click or scan EU-EC-10011533348 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2481 | click or scan EU-EC-10011533306 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2482 | click or scan EU-EC-10011532791 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Night sweats (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2483 | click or scan EU-EC-10011532611 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2484 | click or scan EU-EC-10011532578 | | 2022-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 2485 | click or scan EU-EC-10011532254 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2486 | click or scan EU-EC-10011532199 | | 2022-02-08 | Healthcare Professional | EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 2487 | click or scan EU-EC-10011531781 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2488 | click or scan EU-EC-10011531043 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2489** | click or scan EU-EC-10011530501 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2490** | click or scan EU-EC-10011530423 | | 2022-02-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2491** | click or scan EU-EC-10011530331 | | 2022-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2492** | click or scan EU-EC-10011530289 | | 2022-02-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypertensive nephropathy (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **2493** | click or scan EU-EC-10011526691 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2494** | click or scan EU-EC-10011526141 | | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Immune thrombocytopenia (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **2495** | click or scan EU-EC-10011525769 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2496** | click or scan EU-EC-10011525769 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2497** | click or scan EU-EC-10011525753 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2498** | click or scan EU-EC-10011525498 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haematochezia (n/a - Fatal - **Results in Death**, Life Threatening), Hypoglycaemia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2499 | click or scan EU-EC-10011525498 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haematochezia (n/a - Fatal - **Results in Death**, Life Threatening), Hypoglycaemia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2500 | click or scan EU-EC-10011525456 | | 2022-02-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Gastric haemorrhage (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2501 | click or scan EU-EC-10011525375 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2502 | click or scan EU-EC-10011524897 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2503 | click or scan EU-EC-10011524876 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - ), Concomitant disease progression (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Gastrooesophageal reflux disease (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2504 | click or scan EU-EC-10011524872 | | 2022-02-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bradypnoea (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2505 | click or scan EU-EC-10011524872 | | 2022-02-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bradypnoea (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2506 | click or scan EU-EC-10011524819 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2507 | click or scan EU-EC-10011524819 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2508 | click or scan EU-EC-10011524782 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2509 | click or scan EU-EC-10011524780 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2510 | click or scan EU-EC-10011524772 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2511 | click or scan EU-EC-10011524587 | | 2022-02-07 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - ), Abnormal faeces (n/a - Unknown - ), Cardiac tamponade (n/a - Fatal - **Results in Death**), Chest pain (4d - Recovered/Resolved - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2512 | click or scan EU-EC-10011524343 | | 2022-02-07 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2513 | click or scan EU-EC-10011524094 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dyslalia (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 2514 | click or scan EU-EC-10011524000 | | 2022-02-07 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Venous thrombosis limb (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 2515 | click or scan EU-EC-10011523751 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypotension (n/a - Unknown - Other Medically Important Condition), Leukaemia (n/a - Fatal - **Results in Death**), Lower gastrointestinal haemorrhage (n/a - Unknown - Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2516 | click or scan EU-EC-10011523445 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acetonaemic vomiting (n/a - Fatal - **Results in Death**), Asthma (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2517 | click or scan EU-EC-10011522779 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2518 | click or scan EU-EC-10011522269 | | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2519 | click or scan EU-EC-10011522151 | | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2520 | click or scan EU-EC-10011522142 | | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2521 | click or scan EU-EC-10011522069 | | 2022-02-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2522 | click or scan EU-EC-10011522064 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2523 | click or scan EU-EC-10011521872 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2524 | click or scan EU-EC-10011521573 | | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure congestive (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2525 | click or scan EU-EC-10011519281 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**), Muscle spasms (0d - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 2526 | click or scan EU-EC-10011519034 | | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Male | Aphasia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiplegia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superior sagittal sinus thrombosis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2527 | click or scan EU-EC-10011518960 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), COVID-19 pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), SPIKEVAX DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2528 | click or scan EU-EC-10011518960 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), COVID-19 pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), SPIKEVAX DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2529 | click or scan EU-EC-10011518960 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Unknown - ), COVID-19 pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), SPIKEVAX DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2530 | click or scan EU-EC-10011518523 | | 2022-02-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood glucose increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Clonic convulsion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin degradation products increased (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Meningitis bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Paresis (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2531 | click or scan EU-EC-10011518519 | | 2022-02-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2532 | click or scan EU-EC-10011518035 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2533 | click or scan EU-EC-10011518024 | | 2022-02-07 | Healthcare Professional | EEA | 65-85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Injection site pain (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2534 | click or scan EU-EC-10011518016 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fear (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling hot (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary retention (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2535 | click or scan EU-EC-10011517147 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2536 | click or scan EU-EC-10011517076 |  | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2537 | click or scan EU-EC-10011517041 |  | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Heart rate abnormal (n/a - Unknown - ), Platelet count increased (n/a - Unknown - ), Visual impairment (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2538 | click or scan EU-EC-10011516866 |  | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2539 | click or scan EU-EC-10011516391 |  | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pneumonia viral (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2540 | click or scan EU-EC-10011516238 |  | 2022-02-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 2541 | click or scan EU-EC-10011516164 |  | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2542 | click or scan EU-EC-10011516128 |  | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 2543 | click or scan EU-EC-10011516112 |  | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 2544 | click or scan EU-EC-10011515938 |  | 2022-02-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 2545 | click or scan EU-EC-10011515746 |  | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2546** | click or scan EU-EC-10011515715 | | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2547** | click or scan EU-EC-10011515692 | | 2022-02-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **2548** | click or scan EU-EC-10011515614 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2549** | click or scan EU-EC-10011515606 | | 2022-02-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2550** | click or scan EU-EC-10011515568 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2551** | click or scan EU-EC-10011515203 | | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **2552** | click or scan EU-EC-10011515202 | | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **2553** | click or scan EU-EC-10011515197 | | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Metastasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **2554** | click or scan EU-EC-10011515192 | | 2022-02-07 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (2d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2555** | click or scan EU-EC-10011515189 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **2556** | click or scan EU-EC-10011515186 | | 2022-02-07 | Healthcare Professional | EEA | 65-85 Years | Male | Acute hepatic failure (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug-induced liver injury (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Jaundice (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| **2557** | click or scan EU-EC-10011515183 | | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **2558** | click or scan EU-EC-10011515181 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), [ALGELDRATE, TICK-BORNE ENCEPHALITIS VIRUS (INACTIVATED), NEUDOERFL STRAIN, TICK-BORNE ENCEPHALITIS VIRUS (INACTIVATED), NEUDOERFL STRAIN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), [B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | (B/WASHINGTON/02/2019, WILD TYPE), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **2559** | click or scan EU-EC-10011515179 | | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **2560** | click or scan EU-EC-10011515178 | | 2022-02-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **2561** | click or scan EU-EC-10011515177 | | 2022-02-07 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **2562** | click or scan EU-EC-10011514951 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2563** | click or scan EU-EC-10011514717 | | 2022-02-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2564 | click or scan EU-EC-10011514688 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 2565 | click or scan EU-EC-10011514685 | | 2022-02-07 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2566 | click or scan EU-EC-10011514679 | | 2022-02-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 2567 | click or scan EU-EC-10011514674 | | 2022-02-07 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2568 | click or scan EU-EC-10011514453 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2569 | click or scan EU-EC-10011513950 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2570 | click or scan EU-EC-10011513716 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2571 | click or scan EU-EC-10011513450 | | 2022-02-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2572 | click or scan EU-EC-10011513124 | | 2022-02-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2573 | click or scan EU-EC-10011513086 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Infective exacerbation of chronic obstructive airways disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2574 | click or scan EU-EC-10011512939 | | 2022-02-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2575 | click or scan EU-EC-10011512925 | | 2022-02-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 2576 | click or scan EU-EC-10011512847 | | 2022-02-07 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (55d - Fatal - **Results in Death**), Confusional state (55d - Fatal - **Results in Death**), Hypotension (55d - Fatal - **Results in Death**), Pyrexia (55d - Fatal - **Results in Death**), Septic shock (55d - Fatal - **Results in Death**), Vaccination failure (55d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2577 | click or scan EU-EC-10011512650 | | 2022-02-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 2578 | click or scan EU-EC-10011504659 | | 2022-02-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 2579 | click or scan EU-EC-10011504208 | | 2022-02-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2580 | click or scan EU-EC-10011504072 | | 2022-02-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2581 | click or scan EU-EC-10011504040 | | 2022-02-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Infarction (57d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2582 | click or scan EU-EC-10011504014 | | 2022-02-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Thrombophlebitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2583 | click or scan EU-EC-10011503713 | | 2022-02-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| | | | | | | | | | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), M-M-RVAXPRO [MEASLES VIRUS ENDERS' EDMONSTON STRAIN (LIVE, ATTENUATED), MUMPS VIRUS JERYL LYNN (LEVEL B) STRAIN (LIVE, ATTENUATED), RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED), RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN WI-38 HUMAN DIPLOID LUNG FIBROBLASTS, MUMPS VIRUS JERYL LYNN (LEVEL B) STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK |

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|---|---|---|---|---|---|---|---|---|---|
| **2584** | click or scan<br><br>EU-EC-10011502747 | | 2022-02-05 | Healthcare Professional | EEA | 18-64 Years | Male | Death (27d - Fatal - **Results in Death**) | EMBRYO CELLS, MEASLES VIRUS EDMONSTON-ENDERS STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS (S - Immunisation - n/a - [n/a - n/a - n/a]), [ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FIMBRIAE TYPE 2 AND 3 ADSORBED ON ALUMINIUM PHOSPHATE, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, POLIOVIRUS TYPE 1 (INACTIVATED), POLIOVIRUS TYPE 2 (INACTIVATED), POLIOVIRUS TYPE 3 (INACTIVATED), PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 1 PRODUCED IN VERO CELLS, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 2 PRODUCED IN VERO CELLS, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 3 PRODUCED IN VERO CELLS, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS, POLIOVIRUS TYPE 1, POLIOVIRUS TYPE 2, POLIOVIRUS TYPE 3] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **2585** | click or scan<br><br>EU-EC-10011499949 | | 2022-02-04 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebellar ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2586** | click or scan EU-EC-10011499947 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Memory impairment (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2587** | click or scan EU-EC-10011499942 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Stupor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2588** | click or scan EU-EC-10011499939 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2589** | click or scan EU-EC-10011499915 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [77d - .5mL - Intramuscular]) |
| **2590** | click or scan EU-EC-10011499788 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2591** | click or scan EU-EC-10011499715 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral swelling (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2592** | click or scan EU-EC-10011499680 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Activated partial thromboplastin time prolonged (n/a - Unknown - ), Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**), Constipation (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Faeces discoloured (n/a - Unknown - ), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Grunting (n/a - Fatal - **Results in Death**), Haematochezia (n/a - Fatal - **Results in Death**), Haematocrit decreased (n/a - Unknown - ), Haemorrhage (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lack of spontaneous speech (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mouth haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**), Sneezing (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2593** | click or scan EU-EC-10011499112 | | 2022-02-04 | Non Healthcare Professional | EEA | Not Specified | Male | Immune system disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2594** | click or scan EU-EC-10011498853 | | 2022-02-04 | Non Healthcare Professional | EEA | Not Specified | Male | Off label use (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2595** | click or scan EU-EC-10011498734 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Unknown - ), Musculoskeletal pain (n/a - Unknown - ), Pain (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Rash (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2596** | click or scan<br><br>EU-EC-10011498517 |  | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), [B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **2597** | click or scan<br><br>EU-EC-10011497775 |  | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2598 | click or scan EU-EC-10011497767 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Amnesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cystitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Epistaxis (n/a - Unknown - Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2599 | click or scan EU-EC-10011497752 | | 2022-02-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaphylactic shock (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2600 | click or scan EU-EC-10011497449 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (3d - Fatal - **Results in Death**), Breast pain (3d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Dysphagia (3d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Headache (3d - Fatal - **Results in Death**), Vaccination site pain (3d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2601 | click or scan EU-EC-10011497419 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Irritability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2602 | click or scan EU-EC-10011497306 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (15d - Fatal - **Results in Death**), Vaccination failure (15d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [69d - .5mL - Intramuscular]) |
| 2603 | click or scan EU-EC-10011497194 | | 2022-02-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2604 | click or scan EU-EC-10011497122 | | 2022-02-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2605 | click or scan EU-EC-10011497103 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |
| 2606 | click or scan EU-EC-10011497076 | | 2022-02-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**), Venous thrombosis (19d - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2607 | click or scan EU-EC-10011497048 | | 2022-02-04 | Healthcare Professional | EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2608 | click or scan EU-EC-10011497002 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2609 | click or scan EU-EC-10011496852 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bedridden (1d - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**), Malaise (1d - Recovered/Resolved - ), Vaccination site pain (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2610 | click or scan EU-EC-10011496846 | | 2022-02-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Fatal - **Results in Death**), Constipation (n/a - Fatal - **Results in Death**), Diverticulitis (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intestinal perforation (n/a - Fatal - **Results in Death**), Large intestinal obstruction (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Swelling (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2611 | click or scan EU-EC-10011496841 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2612 | click or scan EU-EC-10011496837 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haematoma (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ventricular rupture (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Unknown - ), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2613 | click or scan EU-EC-10011496823 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac flutter (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2614 | click or scan EU-EC-10011496290 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 2615 | click or scan EU-EC-10011496116 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Near drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2616 | click or scan EU-EC-10011496109 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2617 | click or scan EU-EC-10011496102 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Chest discomfort (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2618 | click or scan EU-EC-10011496101 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aerophobia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hydrophobia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2619 | click or scan EU-EC-10011496096 | | 2022-02-04 | Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2620 | click or scan EU-EC-10011496095 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Embolic stroke (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2621 | click or scan EU-EC-10011496085 | | 2022-02-04 | Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2622 | click or scan EU-EC-10011496084 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain injury (n/a - Unknown - Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2623 | click or scan EU-EC-10011496083 | | 2022-02-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2624 | click or scan EU-EC-10011496063 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2625 | click or scan EU-EC-10011496057 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2626 | click or scan EU-EC-10011496045 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiomyopathy (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Feeling of body temperature change (n/a - Unknown - ), Influenza like illness (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2627** | click or scan EU-EC-10011496044 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Basal ganglia haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hydrocephalus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2628** | click or scan EU-EC-10011496040 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coma (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2629** | click or scan EU-EC-10011495997 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **2630** | click or scan EU-EC-10011495950 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2631** | click or scan EU-EC-10011495756 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Acute polyneuropathy (n/a - Fatal - **Results in Death**), Anaemia (n/a - Fatal - **Results in Death**), Anuria (n/a - Fatal - **Results in Death**), Cardiomyopathy (n/a - Fatal - **Results in Death**), Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia (n/a - Fatal - **Results in Death**), Hepatic lesion (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Quadriplegia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Rhabdomyolysis (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Tracheobronchitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Intramuscular]) |
| **2632** | click or scan EU-EC-10011495005 | | 2022-02-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chronic respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening), Dehydration (n/a - Fatal - **Results in Death**), Malnutrition (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2633** | click or scan EU-EC-10011494987 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriosclerosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), CSF glucose increased (n/a - Unknown - Other Medically Important Condition), CSF protein increased (n/a - Unknown - Other Medically Important Condition), Cytomegalovirus test positive (n/a - Unknown - ), Myelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neuromyelitis optica spectrum disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ovarian cyst (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pneumothorax (n/a - Unknown - Other Medically Important Condition), Rectal ulcer (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition), Thrombotic cerebral infarction (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2634 | click or scan EU-EC-10011494552 | | 2022-02-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Basal ganglia stroke (61d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2635 | click or scan EU-EC-10011494374 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2636 | click or scan EU-EC-10011494197 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2637 | click or scan EU-EC-10011494159 | | 2022-02-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2638 | click or scan EU-EC-10011493838 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 2639 | click or scan EU-EC-10011493763 | | 2022-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Vaccination site pain (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2640 | click or scan EU-EC-10011493715 | | 2022-02-04 | Healthcare Professional | EEA | 18-64 Years | Male | Coma (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2641 | click or scan EU-EC-10011493448 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), COVID-19 (10d - Recovered/Resolved - Other Medically Important Condition), Functional gastrointestinal disorder (n/a - Unknown - Other Medically Important Condition), Gastric cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2642 | click or scan EU-EC-10011493444 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pericardial haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [0y - n/a - Intramuscular]) |
| 2643 | click or scan EU-EC-10011493415 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2644 | click or scan EU-EC-10011493411 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2645 | click or scan EU-EC-10011493411 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2646 | click or scan EU-EC-10011493410 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2647 | click or scan EU-EC-10011492785 | | 2022-02-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac disorder (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2648 | click or scan EU-EC-10011492363 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2649 | click or scan EU-EC-10011492096 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cognitive disorder (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urosepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2650 | click or scan EU-EC-10011492093 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2651 | click or scan EU-EC-10011492038 | | 2022-02-04 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2652 | click or scan EU-EC-10011492037 | | 2022-02-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2653 | click or scan EU-EC-10011492030 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Choking (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Crying (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Eye pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Haemoptysis (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Increased upper airway secretion (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Thrombotic stroke (n/a - Fatal - **Results in Death**), Vision blurred (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2654 | click or scan EU-EC-10011492020 | | 2022-02-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Arterial thrombosis (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**), Gastrointestinal disorder (n/a - Unknown - ), Influenza like illness (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Small intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site erythema (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vaccination site rash (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2655 | click or scan EU-EC-10011491989 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Fatal - **Results in Death**), Angioedema (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Bronchospasm (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Feeling of body temperature change (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Mouth ulceration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Urticaria (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2656 | click or scan EU-EC-10011491948 | | 2022-02-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2657 | click or scan EU-EC-10011491935 | | 2022-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bronchospasm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2658 | click or scan EU-EC-10011491903 | | 2022-02-04 | Non Healthcare Professional | EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2659 | click or scan EU-EC-10011491834 | | 2022-02-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypopnoea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2660 | click or scan EU-EC-10011491528 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2661 | click or scan EU-EC-10011491527 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2662 | click or scan EU-EC-10011490687 | | 2022-02-04 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2663 | click or scan EU-EC-10011490631 | | 2022-02-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arterial thrombosis (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2664 | click or scan EU-EC-10011490075 | | 2022-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2665 | click or scan EU-EC-10011489224 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2666 | click or scan EU-EC-10011489125 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**), Epilepsy (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Movement disorder (32d - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Paralysis (32d - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Rehabilitation therapy (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (32d - Fatal - **Results in Death**, Disabling, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 2667 | click or scan EU-EC-10011488321 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 2668 | click or scan EU-EC-10011487710 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Cerebral disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2669 | click or scan EU-EC-10011487608 | | 2022-02-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2670 | click or scan EU-EC-10011487021 | | 2022-02-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2671 | click or scan EU-EC-10011486933 | | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2672 | click or scan EU-EC-10011486517 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (215d - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombosis (215d - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Parenteral]) |
| 2673 | click or scan EU-EC-10011485974 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2674 | click or scan EU-EC-10011485930 | | 2022-02-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bacteraemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiorenal syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypernatraemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urosepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2675 | click or scan EU-EC-10011485919 | | 2022-02-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2676 | click or scan EU-EC-10011485808 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2677 | click or scan EU-EC-10011485751 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Hospitalisation (5wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2678 | click or scan EU-EC-10011485642 | | 2022-02-03 | Healthcare Professional | EEA | 18-64 Years | Male | Multiple organ dysfunction syndrome (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2679 | click or scan EU-EC-10011485539 | | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypotension (n/a - Fatal - **Results in Death**, Life Threatening), Syncope (n/a - Fatal - **Results in Death**, Life Threatening), Tachycardia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2680 | click or scan EU-EC-10011484832 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2681 | click or scan EU-EC-10011484813 | | 2022-02-03 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 2682 | click or scan EU-EC-10011484794 | | 2022-02-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2683 | click or scan EU-EC-10011484680 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [113d - 2 {DF} - Intramuscular]) |
| 2684 | click or scan EU-EC-10011484680 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [113d - 2 {DF} - Intramuscular]) |
| 2685 | click or scan EU-EC-10011484524 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2686 | click or scan EU-EC-10011484307 | | 2022-02-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Drug level increased (n/a - Recovering/Resolving - ), Troponin increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [CLOZAPINE] (S - Schizophrenia - Not applicable - [n/a - 425mg - Oral]) |
| 2687 | click or scan EU-EC-10011483927 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2688 | click or scan EU-EC-10011483441 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2689 | click or scan EU-EC-10011483148 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Illusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2690** | click or scan EU-EC-10011483109 | | 2022-02-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2691** | click or scan EU-EC-10011482848 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aortic thrombosis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leriche syndrome (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2692** | click or scan EU-EC-10011481999 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2693** | click or scan EU-EC-10011481937 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **2694** | click or scan EU-EC-10011481856 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **2695** | click or scan EU-EC-10011481162 | | 2022-02-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Abnormal behaviour (n/a - Unknown - ), Amnesia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Disturbance in attention (n/a - Unknown - ), Epistaxis (n/a - Unknown - ), Fall (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Indifference (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | [ACICLOVIR, ACICLOVIR SODIUM] (S - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2696** | click or scan EU-EC-10011480266 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Nervous system disorder (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **2697** | click or scan EU-EC-10011480125 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **2698** | click or scan EU-EC-10011480086 | | 2022-02-03 | Healthcare Professional | EEA | 65-85 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |
| **2699** | click or scan EU-EC-10011480071 | | 2022-02-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2700** | click or scan EU-EC-10011480000 |  | 2022-02-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **2701** | click or scan EU-EC-10011479688 |  | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2702** | click or scan EU-EC-10011479636 |  | 2022-02-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2703** | click or scan EU-EC-10011479610 |  | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2704** | click or scan EU-EC-10011479608 |  | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2705** | click or scan EU-EC-10011479376 |  | 2022-02-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2706** | click or scan EU-EC-10011479364 |  | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Sepsis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **2707** | click or scan EU-EC-10011479250 |  | 2022-02-03 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhage coronary artery (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **2708** | click or scan EU-EC-10011479104 |  | 2022-02-03 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| **2709** | click or scan EU-EC-10011479080 |  | 2022-02-03 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2710 | click or scan EU-EC-10011479059 | | 2022-02-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2711 | click or scan EU-EC-10011478610 | | 2022-02-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2712 | click or scan EU-EC-10011478582 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2713 | click or scan EU-EC-10011478488 | | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2714 | click or scan EU-EC-10011478400 | | 2022-02-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 2715 | click or scan EU-EC-10011478182 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 2716 | click or scan EU-EC-10011477869 | | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 2717 | click or scan EU-EC-10011477867 | | 2022-02-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (6d - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2718 | click or scan EU-EC-10011477777 | | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2719 | click or scan EU-EC-10011477777 | | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2720 | click or scan EU-EC-10011477667 | | 2022-02-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2721 | click or scan EU-EC-10011477061 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (3d - Fatal - **Results in Death**), Cardiac failure (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 2722 | click or scan EU-EC-10011476592 | | 2022-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 2723 | click or scan EU-EC-10011476581 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 2724 | click or scan EU-EC-10011476443 | | 2022-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2725 | click or scan EU-EC-10011475208 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2726 | click or scan EU-EC-10011475169 | | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2727 | click or scan EU-EC-10011474522 | | 2022-02-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain herniation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhage intracranial (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypernatraemia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Loss of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Photophobia (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Prophylaxis of nausea and vomiting (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2728** | click or scan EU-EC-10011474267 |  | 2022-02-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Leukaemia monocytic (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral circulatory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **2729** | click or scan EU-EC-10011473201 |  | 2022-02-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2730** | click or scan EU-EC-10011472058 |  | 2022-02-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2731** | click or scan EU-EC-10011472015 |  | 2022-02-02 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2732** | click or scan EU-EC-10011471950 |  | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Bradykinesia (n/a - Unknown - ), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Incoherent (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **2733** | click or scan EU-EC-10011471444 |  | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **2734** | click or scan EU-EC-10011471415 |  | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **2735** | click or scan EU-EC-10011471404 |  | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2736** | click or scan EU-EC-10011471382 |  | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2737 | click or scan EU-EC-10011471380 | | 2022-02-02 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), STALEVO [CARBIDOPA, ENTACAPONE, LEVODOPA] (S - Extrapyramidal disorder - Dose not changed - [n/a - n/a - n/a]), [FLUOXETINE HYDROCHLORIDE] (S - Depression - Dose not changed - [n/a - n/a - n/a]), [MIDODRINE HYDROCHLORIDE] (S - Orthostatic hypotension - Dose not changed - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (S - Pain in extremity - Dose not changed - [n/a - n/a - n/a]) |
| 2738 | click or scan EU-EC-10011471379 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2739 | click or scan EU-EC-10011471313 | | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 2740 | click or scan EU-EC-10011471295 | | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [26d - 2{DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 2741 | click or scan EU-EC-10011471295 | | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [26d - 2{DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 2742 | click or scan EU-EC-10011471290 | | 2022-02-02 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Heart disease congenital (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Transplacental]) |
| 2743 | click or scan EU-EC-10011471235 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Intramuscular]) |
| 2744 | click or scan EU-EC-10011470635 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Pulmonary haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2745 | click or scan EU-EC-10011470631 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 2746 | click or scan EU-EC-10011470577 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myocardial infarction (13d - Fatal - **Results in Death**), Pericarditis (13d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 2747 | click or scan EU-EC-10011470378 | | 2022-02-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Echocardiogram (n/a - Unknown - ), Endocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Melaena (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2748 | click or scan EU-EC-10011470064 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 2749 | click or scan EU-EC-10011470032 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2750 | click or scan EU-EC-10011469599 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | Accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Contusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Craniocerebral injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Subdural haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 2751 | click or scan EU-EC-10011469327 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2752 | click or scan EU-EC-10011468627 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (n/a - Unknown - ), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Internal haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (n/a - Unknown - ), Pain (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 2753 | click or scan EU-EC-10011468432 | | 2022-02-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2754 | click or scan EU-EC-10011467753 | | 2022-02-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2755 | click or scan EU-EC-10011467043 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2756 | click or scan EU-EC-10011466975 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Epistaxis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ichthyosis acquired (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pemphigoid (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Purpura (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 2757 | click or scan EU-EC-10011466887 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (86d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Metastases to central nervous system (86d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neoplasm progression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nervous system disorder (86d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 2758 | click or scan EU-EC-10011466592 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (42d - Fatal - **Results in Death**, Other Medically Important Condition), Muscle spasms (42d - Fatal - **Results in Death**, Other Medically Important Condition), Pigmentation disorder (42d - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2759 | click or scan EU-EC-10011466575 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular - More in ICSR]) |
| 2760 | click or scan EU-EC-10011466409 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**), Malaise (1wk - Fatal - **Results in Death**), Pulse absent (0d - Fatal - **Results in Death**), Respiratory arrest (0d - Fatal - **Results in Death**), Sudden cardiac death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Intramuscular]) |
| 2761 | click or scan EU-EC-10011466408 | | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Agonal respiration (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 2762 | click or scan EU-EC-10011466357 | | 2022-02-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2763 | click or scan EU-EC-10011465785 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory distress syndrome (252d - Fatal - **Results in Death**), Altered state of consciousness (252d - Fatal - **Results in Death**), Anaemia macrocytic (252d - Fatal - **Results in Death**), Apathy (252d - Fatal - **Results in Death**), Asthenia (252d - Fatal - **Results in Death**), Autoimmune disorder (252d - Fatal - **Results in Death**), Autoimmune lung disease (252d - Fatal - **Results in Death**), Cough (252d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Dyspnoea (252d - Fatal - **Results in Death**), General physical health deterioration (252d - Fatal - **Results in Death**), Haemoglobin decreased (252d - Fatal - **Results in Death**), Interstitial lung disease (252d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (252d - Fatal - **Results in Death**), Organising pneumonia (252d - Fatal - **Results in Death**), Oxygen saturation decreased (252d - Fatal - **Results in Death**), Pleural effusion (252d - Fatal - **Results in Death**), Pneumonia aspiration (252d - Fatal - **Results in Death**), Renal failure (252d - Fatal - **Results in Death**), Somnolence (252d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2764 | click or scan EU-EC-10011465707 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Coronary artery disease (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Visual impairment (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 2765 | click or scan EU-EC-10011465638 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 2766 | click or scan EU-EC-10011465610 | | 2022-02-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2767 | click or scan EU-EC-10011465598 | | 2022-02-02 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2768 | click or scan EU-EC-10011465558 | | 2022-02-02 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 2769 | click or scan EU-EC-10011465555 | | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 2770 | click or scan EU-EC-10011465547 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myeloid leukaemia recurrent (3mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a - More in ICSR]) |
| 2771 | click or scan EU-EC-10011465535 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Balance disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Memory impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2772 | click or scan EU-EC-10011465356 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2773 | click or scan EU-EC-10011465219 | | 2022-02-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute pulmonary oedema (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 2774 | click or scan EU-EC-10011465136 | | 2022-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematoma (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2775 | click or scan EU-EC-10011464883 | | 2022-02-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cachexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dementia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2776 | click or scan EU-EC-10011464882 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2777 | click or scan EU-EC-10011464731 | | 2022-02-02 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2778 | click or scan EU-EC-10011464486 | | 2022-02-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2779 | click or scan EU-EC-10011464356 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cytokine storm (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2780 | click or scan EU-EC-10011464309 | | 2022-02-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2781 | click or scan EU-EC-10011463964 | | 2022-02-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebellar haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2782 | click or scan EU-EC-10011463637 | | 2022-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2783 | click or scan EU-EC-10011463511 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Male | Coma (4d - Fatal - **Results in Death**), Headache (4d - Fatal - **Results in Death**), Mydriasis (4d - Fatal - **Results in Death**), Subdural haematoma (4d - Fatal - **Results in Death**), Vomiting (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2784 | click or scan EU-EC-10011463382 | | 2022-02-02 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (3d - Fatal - **Results in Death**), Ischaemic stroke (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2785 | click or scan EU-EC-10011463350 | | 2022-02-02 | Non Healthcare Professional | EEA | More than 85 Years | Male | Aphthous ulcer (69d - Fatal - **Results in Death**), Internal haemorrhage (69d - Fatal - **Results in Death**), Tooth loss (69d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 2786 | click or scan EU-EC-10011462579 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Gastrointestinal disorder (n/a - Fatal - **Results in Death**), Metastatic malignant melanoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myositis (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2787 | click or scan EU-EC-10011461506 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Oedema peripheral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |
| 2788 | click or scan EU-EC-10011461305 | | 2022-02-01 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2789 | click or scan EU-EC-10011461260 | | 2022-02-01 | Healthcare Professional | EEA | Not Specified | Male | Congenital midline defect (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Recovered/Resolved - **Results in Death**, Congenital Anomaly) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| 2790 | click or scan EU-EC-10011460998 | | 2022-02-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Gastric ulcer perforation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 2791 | click or scan EU-EC-10011460809 | | 2022-02-01 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2792 | click or scan EU-EC-10011459790 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [NOT AVAILABLE] (S - Carotid artery stenosis - Not applicable - [n/a - n/a - n/a]) |
| 2793 | click or scan EU-EC-10011459767 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Malaise (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2794 | click or scan EU-EC-10011459702 | | 2022-02-01 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [36d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2795 | click or scan EU-EC-10011459629 | | 2022-02-01 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 2796 | click or scan EU-EC-10011459483 | | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain compression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain neoplasm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebellar haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemangioma (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial aneurysm (n/a - Unknown - Other Medically Important Condition), Meningioma (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tumour haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2797 | click or scan EU-EC-10011459148 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Activated partial thromboplastin time prolonged (n/a - Unknown - ), Alanine aminotransferase increased (n/a - Unknown - Other Medically Important Condition), Amylase increased (n/a - Unknown - Other Medically Important Condition), Aspartate aminotransferase increased (n/a - Unknown - Other Medically Important Condition), Blood creatine phosphokinase MB increased (n/a - Unknown - Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Unknown - Other Medically Important Condition), Blood glucose increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - Other Medically Important Condition), Blood phosphorus increased (n/a - Unknown - ), Blood potassium increased (n/a - Unknown - ), Blood thyroid stimulating hormone increased (n/a - Unknown - ), Brain natriuretic peptide increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Human epidermal growth factor receptor decreased (n/a - Unknown - ), Lymphocyte count increased (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Prothrombin time prolonged (n/a - Unknown - ), Prothrombin time ratio decreased (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2798 | click or scan EU-EC-10011459138 | | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2799 | click or scan EU-EC-10011459134 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Unknown - ), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Immobilisation syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Unknown - ), Productive cough (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2800 | click or scan EU-EC-10011459126 | | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Unknown - ), Back pain (n/a - Unknown - ), Blood pressure increased (n/a - Unknown - ), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Craniocerebral injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Emphysema (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), False lumen dilatation of aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage subcutaneous (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Hypertrophy (n/a - Fatal - **Results in Death**), Neck injury (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Skin laceration (n/a - Unknown - ), Soft tissue haemorrhage (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2801 | click or scan EU-EC-10011459019 | | 2022-02-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral arterial occlusive disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]), PEMBROLIZUMAB [PEMBROLIZUMAB] (S - Non-small cell lung cancer - Drug withdrawn - [n/a - 200mg - Parenteral]) |
| 2802 | click or scan EU-EC-10011458763 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2803 | click or scan EU-EC-10011458093 | | 2022-02-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cerebrospinal fluid retention (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 2804 | click or scan EU-EC-10011456880 | | 2022-02-01 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 2805 | click or scan EU-EC-10011456602 | | 2022-02-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Haematoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Petechiae (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 2806 | click or scan EU-EC-10011456560 | | 2022-02-01 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2807 | click or scan EU-EC-10011455936 | | 2022-02-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Adrenal gland cancer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain cancer metastatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung cancer metastatic (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Meningitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Parenteral]) |
| 2808 | click or scan EU-EC-10011455638 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Moaning (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2809 | click or scan EU-EC-10011455625 | | 2022-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2810 | click or scan EU-EC-10011455443 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (28d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (28d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hand amputation (28d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Myocardial infarction (28d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pneumonia (28d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 2811 | click or scan EU-EC-10011455427 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (10d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Body temperature (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Body temperature increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (10d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - ), Coagulation time shortened (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Costovertebral angle tenderness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flank pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Inflammation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (14d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Limb discomfort (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lower respiratory tract infection (10d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (10d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neck pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (14d - Not Recovered/Not Resolved - ), Sepsis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitic rash (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2812 | click or scan EU-EC-10011455344 | | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [0mo - n/a - Intramuscular]) |
| 2813 | click or scan EU-EC-10011455253 | | 2022-02-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2814 | click or scan EU-EC-10011454902 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood glucose increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Stroke volume increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 2815 | click or scan EU-EC-10011453903 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) DISPERSION FOR INJECTION 30 MICROGRAMS/DOSE [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 2816 | click or scan EU-EC-10011453479 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2817 | click or scan EU-EC-10011453231 | | 2022-02-01 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ), Sleep disorder (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2818 | click or scan EU-EC-10011452821 | | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2819 | click or scan EU-EC-10011452640 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 2820 | click or scan EU-EC-10011452632 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 2821 | click or scan EU-EC-10011452629 | | 2022-02-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2822** | click or scan EU-EC-10011452281 | | 2022-02-01 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrioventricular block complete (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyskinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Facial paresis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Incisional hernia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Memory impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mydriasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet factor 4 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Reflexes abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sinoatrial block (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sinus bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**), Tongue paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tonsillar disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Walking aid user (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **2823** | click or scan EU-EC-10011452272 | | 2022-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Agitation (n/a - Unknown - Caused/Prolonged Hospitalisation), Arterial occlusive disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Skin discolouration (n/a - Unknown - Caused/Prolonged Hospitalisation), Skin erosion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2824** | click or scan EU-EC-10011452266 | | 2022-02-01 | Healthcare Professional | EEA | 18-64 Years | Female | Back pain (19d - Fatal - **Results in Death**), Cerebral haematoma (16d - Fatal - **Results in Death**, Life Threatening), Cerebral venous sinus thrombosis (16d - Fatal - **Results in Death**, Life Threatening), Haemorrhagic cerebral infarction (16d - Fatal - **Results in Death**, Life Threatening), Headache (19d - Fatal - **Results in Death**), Malaise (19d - Fatal - **Results in Death**), Pain in extremity (19d - Fatal - **Results in Death**), Thrombocytopenia (16d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **2825** | click or scan EU-EC-10011452112 | | 2022-02-01 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **2826** | click or scan EU-EC-10011452058 | | 2022-02-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Catastrophic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2827** | click or scan EU-EC-10011451841 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Expired product administered (n/a - Unknown - **Results in Death**), Non-small cell lung cancer (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2828 | click or scan EU-EC-10011451827 | | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Brain death (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cavernous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2829 | click or scan EU-EC-10011451561 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Spontaneous haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2830 | click or scan EU-EC-10011451434 | | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2831 | click or scan EU-EC-10011451306 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 2832 | click or scan EU-EC-10011451239 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Life Threatening), Chest pain (n/a - Recovered/Resolved - Life Threatening), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Not Recovered/Not Resolved - Life Threatening), Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening), Joint swelling (n/a - Not Recovered/Not Resolved - Life Threatening), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening), Myocardial rupture (n/a - Not Recovered/Not Resolved - Life Threatening), Pericardial haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening), Vaccination site pain (n/a - Not Recovered/Not Resolved - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2833 | click or scan EU-EC-10011451012 |  | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood magnesium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Burning sensation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Demyelinating polyneuropathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic steatosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Motor dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Occult blood negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound abdomen abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine analysis abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2834 | click or scan EU-EC-10011450966 |  | 2022-02-01 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Multisystem inflammatory syndrome in adults (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2835 | click or scan EU-EC-10011450913 |  | 2022-02-01 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2836 | click or scan EU-EC-10011450841 |  | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hangover (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (8d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 2837 | click or scan EU-EC-10011450771 |  | 2022-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coma (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple sclerosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2838 | click or scan EU-EC-10011450374 |  | 2022-02-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2839 | click or scan EU-EC-10011450372 |  | 2022-02-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2840** | click or scan EU-EC-10011450370 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **2841** | click or scan EU-EC-10011450364 | | 2022-02-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2842** | click or scan EU-EC-10011448928 | | 2022-02-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **2843** | click or scan EU-EC-10011448878 | | 2022-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **2844** | click or scan EU-EC-10011447888 | | 2022-01-31 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2845** | click or scan EU-EC-10011447560 | | 2022-01-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain stem auditory evoked response abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cerebral ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coordination abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dyskinesia (n/a - Fatal - **Results in Death**), Essential hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Incorrect route of product administration (n/a - Unknown - ), Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lip disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Presbyacusis (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2846** | click or scan EU-EC-10011447538 | | 2022-01-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Communication disorder (n/a - Unknown - ), Ischaemic stroke (n/a - Unknown - Life Threatening, Other Medically Important Condition), Nervous system disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2847 | click or scan EU-EC-10011446660 | | 2022-01-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2848 | click or scan EU-EC-10011446657 | | 2022-01-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Anaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Anxiety (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Aphonia (6d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dysgeusia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (11d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Influenza like illness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Joint swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Night sweats (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain in extremity (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Parosmia (9d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), T-cell lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tongue abscess (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)... | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2849 | click or scan EU-EC-10011446335 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Application site discomfort (n/a - Fatal - **Results in Death**), Brain death (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2850 | click or scan EU-EC-10011445355 | | 2022-01-31 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 2851 | click or scan EU-EC-10011445352 | | 2022-01-31 | Non Healthcare Professional | EEA | 18-64 Years | Male | Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2852 | click or scan EU-EC-10011444695 | | 2022-01-31 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 2853 | click or scan EU-EC-10011444117 | | 2022-01-31 | Healthcare Professional | EEA | 18-64 Years | Female | Intestinal ischaemia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 2854 | click or scan EU-EC-10011444103 | | 2022-01-31 | Healthcare Professional | EEA | 65-85 Years | Male | Dehydration (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Delirium (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2855 | click or scan EU-EC-10011443843 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2856 | click or scan EU-EC-10011443423 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2857 | click or scan EU-EC-10011443393 | | 2022-01-31 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2858 | click or scan EU-EC-10011443158 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2859 | click or scan EU-EC-10011442736 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2860 | click or scan EU-EC-10011442657 | | 2022-01-31 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Feeling abnormal (89d - Fatal - **Results in Death**), Headache (89d - Fatal - **Results in Death**), Internal haemorrhage (89d - Fatal - **Results in Death**), Visceral pain (89d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 2861 | click or scan EU-EC-10011441941 | | 2022-01-31 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2862 | click or scan EU-EC-10011441880 | | 2022-01-31 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal discomfort (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2863 | click or scan EU-EC-10011441757 | | 2022-01-31 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2864 | click or scan EU-EC-10011441464 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Discomfort (1d - Recovered/Resolved - ), Dizziness (1d - Recovered/Resolved - ), Feeling of body temperature change (1d - Recovered/Resolved - ), Pulmonary thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2865 | click or scan EU-EC-10011440286 | | 2022-01-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood fibrinogen decreased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haematoma (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Decompressive craniectomy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Influenza A virus test negative (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Influenza B virus test (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Influenza virus test negative (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mucosal hypertrophy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neutrophilia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pupillary reflex impaired (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory syncytial virus test negative (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2866 | click or scan EU-EC-10011440145 | | 2022-01-31 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2867 | click or scan EU-EC-10011440136 | | 2022-01-31 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cachexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Mental impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2868 | click or scan EU-EC-10011440135 | | 2022-01-31 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Leukocytosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2869 | click or scan EU-EC-10011440129 | | 2022-01-31 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2870 | click or scan EU-EC-10011440111 | | 2022-01-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2871 | click or scan EU-EC-10011440046 | | 2022-01-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2872 | click or scan EU-EC-10011439951 | | 2022-01-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2873 | click or scan EU-EC-10011439680 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2874 | click or scan EU-EC-10011439472 | | 2022-01-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2875 | click or scan EU-EC-10011438761 | | 2022-01-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2876 | click or scan EU-EC-10011438761 | | 2022-01-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2877 | click or scan EU-EC-10011438715 | | 2022-01-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2878 | click or scan EU-EC-10011438715 | | 2022-01-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2879 | click or scan EU-EC-10011438553 | | 2022-01-31 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 2880 | click or scan EU-EC-10011438552 | | 2022-01-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 2881 | click or scan EU-EC-10011438551 | | 2022-01-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abscess drainage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Abscess limb (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Caregiver (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dementia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site reaction (n/a - Not Recovered/Not Resolved - ), Weight decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 2882 | click or scan EU-EC-10011437535 | | 2022-01-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2883 | click or scan EU-EC-10011437378 | | 2022-01-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 2884 | click or scan EU-EC-10011437165 | | 2022-01-31 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 2885 | click or scan EU-EC-10011436531 | | 2022-01-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2886 | click or scan EU-EC-10011436072 | | 2022-01-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2887 | click or scan EU-EC-10011431871 | | 2022-01-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arteriosclerosis (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Cardiac failure chronic (0d - Fatal - **Results in Death**), Cardiac failure congestive (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Injection site swelling (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2888 | click or scan EU-EC-10011430963 | | 2022-01-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Angiogram cerebral abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vertigo (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vision blurred (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 2889 | click or scan EU-EC-10011430914 | | 2022-01-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 2890 | click or scan EU-EC-10011430834 | | 2022-01-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 2891 | click or scan EU-EC-10011430647 | | 2022-01-30 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2892 | click or scan EU-EC-10011430413 | | 2022-01-30 | Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2893 | click or scan EU-EC-10011430273 | | 2022-01-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product use issue (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [ALUMINIUM, HEPATITIS B SURFACE ANTIGEN (RDNA) ADSORBED ON ALUMINIUM HYDROXIDE [PRODUCED IN S. CEREVISIAE (STRAIN 2150-2-3) BY RDNA], ALUMINIUM, HEPATITIS B SURFACE ANTIGEN (RDNA) [PRODUCED IN S. CEREVISIAE CELLS BY RDNA], HEPATITIS B SURFACE ANTIGEN (RDNA), HEPATITIS B SURFACE ANTIGEN (RDNA) ADSORBED ON ALUMINIUM HYDROXIDE [PRODUCED IN S. CEREVISIAE (STRAIN 2150-2-3) BY RDNA], ALGELDRATE, HEPATITIS B SURFACE ANTIGEN (RDNA) [PRODUCED IN S. CEREVISIAE CELLS BY RDNA], ALGELDRATE, HEPATITIS B SURFACE ANTIGEN, ALGELDRATE, HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED, ALGELDRATE] (S - Immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2894 | click or scan EU-EC-10011430110 | | 2022-01-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 2895 | click or scan EU-EC-10011430084 | | 2022-01-30 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2896 | click or scan EU-EC-10011429412 | | 2022-01-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - Unknown]) |
| 2897 | click or scan EU-EC-10011427921 | | 2022-01-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (4d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 2898 | click or scan EU-EC-10011427667 | | 2022-01-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| 2899 | click or scan EU-EC-10011426776 | | 2022-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 2900 | click or scan EU-EC-10011425993 | | 2022-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Cognitive disorder (n/a - Fatal - **Results in Death**), Hypokinesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 2901 | click or scan EU-EC-10011425966 | | 2022-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Embolism (12d - Fatal - **Results in Death**), Sepsis (12d - Fatal - **Results in Death**), Thrombosis (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 2902 | click or scan EU-EC-10011425960 | | 2022-01-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Encephalitis (170d - Fatal - **Results in Death**), Variant Creutzfeldt-Jakob disease (170d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2903 | click or scan EU-EC-10011425954 | | 2022-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2904** | click or scan EU-EC-10011425926 |  | 2022-01-29 | Healthcare Professional | EEA | 65-85 Years | Male | Hyperleukocytosis (121d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2905** | click or scan EU-EC-10011425924 |  | 2022-01-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Brain stem ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **2906** | click or scan EU-EC-10011425916 |  | 2022-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Spinal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2907** | click or scan EU-EC-10011425911 |  | 2022-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]), FLUAD TETRA [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **2908** | click or scan EU-EC-10011425899 |  | 2022-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **2909** | click or scan EU-EC-10011425885 |  | 2022-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2910** | click or scan EU-EC-10011425882 |  | 2022-01-29 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2911** | click or scan EU-EC-10011425874 |  | 2022-01-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **2912** | click or scan EU-EC-10011425868 |  | 2022-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Meningitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2913 | click or scan EU-EC-10011425836 | | 2022-01-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebellar stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2914 | click or scan EU-EC-10011425701 | | 2022-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 2915 | click or scan EU-EC-10011425560 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2916 | click or scan EU-EC-10011425481 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injection site pain (n/a - Unknown - ), Nausea (n/a - Unknown - ), Neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 2917 | click or scan EU-EC-10011425057 | | 2022-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2918 | click or scan EU-EC-10011424792 | | 2022-01-28 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2919 | click or scan EU-EC-10011424678 | | 2022-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), FLUCELVAX TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE [B/PHUKET/3073/2013-LIKE VIRUS (B/SINGAPORE/INFTT-16-0610/2016, WILD TYPE), B/WASHINGTON/02/2019-LIKE VIRUS (B/DARWIN/7/2019, WILD TYPE), A/WISCONSIN/588/2019 (H1N1)PDM09-LIKE STRAIN (A/WASHINGTON/19/2020, WILD TYPE), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/TASMANIA/503/2020, WILD TYPE)] (S - Influenza immunisation - Not applicable - [1d - n/a - n/a]) |
| 2920 | click or scan EU-EC-10011424663 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Application site pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2921 | click or scan EU-EC-10011424583 | | 2022-01-28 | Healthcare Professional | EEA | 18-64 Years | Male | Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 2922 | click or scan EU-EC-10011424476 | | 2022-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2923 | click or scan EU-EC-10011424210 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 2924 | click or scan EU-EC-10011424011 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 2925 | click or scan EU-EC-10011423926 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain herniation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Facial paresis (n/a - Unknown - Caused/Prolonged Hospitalisation), Flank pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Nerve compression (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2926 | click or scan EU-EC-10011423619 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2927 | click or scan EU-EC-10011423543 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2928** | click or scan EU-EC-10011423157 | | 2022-01-28 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Foetal heart rate decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Stillbirth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **2929** | click or scan EU-EC-10011423154 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2930** | click or scan EU-EC-10011423149 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2931** | click or scan EU-EC-10011423146 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Urinary incontinence (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2932** | click or scan EU-EC-10011422950 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Atrioventricular block second degree (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2933** | click or scan EU-EC-10011421968 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anosmia (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovering/Resolving - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2934** | click or scan EU-EC-10011421832 | | 2022-01-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Skin discolouration (n/a - Unknown - ), Skin plaque (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2935** | click or scan EU-EC-10011421298 | | 2022-01-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2936** | click or scan<br><br>EU-EC-10011421203 | | 2022-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, X-181), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), B/MASSACHUSETTS/2/2012-LIKE STRAIN (B/MASSACHUSETTS/2/2012, BX-51B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B)] (S - Influenza immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2937 | click or scan EU-EC-10011421190 | | 2022-01-28 | Healthcare Professional | EEA | Not Specified | Male | Urethral valves (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental]), ENOXAPARIN SODIUM [ENOXAPARIN SODIUM] (S - Prophylaxis - Not applicable - [6d - 4000[iU] - Transplacental]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (S - Gastrooesophageal reflux disease - Not applicable - [1d - 20mg - Transplacental]), [AMOXICILLIN, AMOXICILLIN SODIUM, AMOXICILLIN TRIHYDRATE] (S - Appendicitis perforated - Not applicable - [1d - 3g - Transplacental]), [ANHYDROUS ROPIVACAINE HYDROCHLORIDE, ROPIVACAINE HYDROCHLORIDE MONOHYDRATE] (S - Anaesthesia - Not applicable - [1d - 20mL - Transplacental]), [CEFOTAXIME, CEFOTAXIME SODIUM, CEFOTAXIME SODIUM STERILE] (S - Appendicitis perforated - Not applicable - [5d - 3g - Transplacental]), [CLAVULANIC ACID] (S - Appendicitis perforated - Not applicable - [1d - 275mg - Transplacental]), [LEVOTHYROXINE SODIUM] (S - COVID-19 immunisation - Not applicable - [167d - 50ug - Transplacental]), [METRONIDAZOLE] (S - Appendicitis perforated - Not applicable - [5d - 3g - Transplacental]), [NEFOPAM HYDROCHLORIDE] (S - Pain - Not applicable - [3d - 80mg - Transplacental]), [ONDANSETRON HYDROCHLORIDE] (S - Nausea - Not applicable - [5d - 16mg - Transplacental]), [PARACETAMOL] (S - Pain - Not applicable - [8d - 4g - Transplacental]), [PHLOROGLUCINOL] (S - Pain - Not applicable - [8d - 240mg - Transplacental]), [SERTACONAZOLE NITRATE] (S - Vulvovaginal mycotic infection - Not applicable - [1d - 1{DF} - Transplacental]), [TRAMADOL HYDROCHLORIDE] (S - Pain - Not applicable - [8d - 100mg - Transplacental]) |
| 2938 | click or scan EU-EC-10011421142 | | 2022-01-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) |
| 2939 | click or scan EU-EC-10011421094 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2940 | click or scan EU-EC-10011421000 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2941 | click or scan EU-EC-10011420888 | | 2022-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2942 | click or scan EU-EC-10011420718 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chronic respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 2943 | click or scan EU-EC-10011420310 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| 2944 | click or scan EU-EC-10011420310 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| 2945 | click or scan EU-EC-10011420172 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2946 | click or scan EU-EC-10011420034 | | 2022-01-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multisystem inflammatory syndrome in adults (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 2947 | click or scan EU-EC-10011420002 | | 2022-01-28 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2948 | click or scan EU-EC-10011419881 | | 2022-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Respiratory tract infection (4d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 2949 | click or scan EU-EC-10011419878 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Fatal - **Results in Death**), Altered state of consciousness (n/a - Fatal - **Results in Death**), Anuria (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2950 | click or scan EU-EC-10011419774 | | 2022-01-28 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2951 | click or scan EU-EC-10011419447 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2952 | click or scan EU-EC-10011419398 | | 2022-01-28 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), VENETOCLAX [VENETOCLAX] (S - Acute myeloid leukaemia - Not applicable - [n/a - 100mg - Oral]), VIDAZA [AZACITIDINE] (S - Acute myeloid leukaemia - Not applicable - [n/a - 37.5mg/m2 - Subcutaneous]) |
| 2953 | click or scan EU-EC-10011419245 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Haemoptysis (1d - Recovered/Resolved - Other Medically Important Condition), Illness (n/a - Unknown - ), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Panic attack (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2954 | click or scan EU-EC-10011419229 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (3mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Guillain-Barre syndrome (3mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2955 | click or scan EU-EC-10011419223 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion (n/a - Fatal - **Results in Death**), Headache (n/a - Recovered/Resolved - ), Pain (n/a - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2956 | click or scan EU-EC-10011418946 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2957 | click or scan EU-EC-10011418613 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Osteomyelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 2958 | click or scan EU-EC-10011418202 | | 2022-01-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Colon cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 2959 | click or scan EU-EC-10011418115 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 2960 | click or scan EU-EC-10011417885 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Emphysema (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 2961 | click or scan EU-EC-10011417846 | | 2022-01-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2962 | click or scan EU-EC-10011417057 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2963 | click or scan EU-EC-10011416998 | | 2022-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2964 | click or scan EU-EC-10011416481 | | 2022-01-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2965 | click or scan EU-EC-10011416340 | | 2022-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dry mouth (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 2966 | click or scan EU-EC-10011416177 | | 2022-01-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 2967 | click or scan EU-EC-10011416116 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diet refusal (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2968 | click or scan EU-EC-10011416044 | | 2022-01-28 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 2969 | click or scan EU-EC-10011415924 | | 2022-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cough (3d - Fatal - **Results in Death**), Haemoptysis (3d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2970 | click or scan EU-EC-10011415861 | | 2022-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Influenza (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 2971 | click or scan EU-EC-10011415795 | | 2022-01-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiopulmonary failure (0d - Fatal - **Results in Death**), Myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 2972 | click or scan EU-EC-10011415479 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2973 | click or scan EU-EC-10011415412 | | 2022-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 2974 | click or scan EU-EC- | | 2022-01-28 | Healthcare Professional | EEA | 65-85 Years | Female | Anaphylactic shock (2h - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), |

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| # | 10011415305<br><br>**EU Local Number** | | **EV Gateway Receipt Date** | **Primary Source Qualification** | **Primary Source Country for Regulatory Purposes** | **Patient Age Group** | **Patient Sex** | **Reaction List PT (Duration - Outcome - Seriousness Criteria)** | **Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)** B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **2975** | click or scan<br><br>EU-EC-10011414876 | | 2022-01-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **2976** | click or scan<br><br>EU-EC-10011414868 | | 2022-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **2977** | click or scan<br><br>EU-EC-10011414795 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Anaemia (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematochezia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition), Lung opacity (n/a - Unknown - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Melaena (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**), Thrombocytopenic purpura (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2978 | click or scan EU-EC-10011414735 | | 2022-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 2979 | click or scan EU-EC-10011414719 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Illness (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 2980 | click or scan EU-EC-10011414281 | | 2022-01-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 2981 | click or scan EU-EC-10011413928 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2982 | click or scan EU-EC-10011413921 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 2983 | click or scan EU-EC-10011413689 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia aspiration (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 2984 | click or scan EU-EC-10011413501 | | 2022-01-28 | Healthcare Professional | EEA | 65-85 Years | Female | Bacterial colitis (167d - Fatal - **Results in Death**), Bacterial sepsis (167d - Fatal - **Results in Death**), Diarrhoea (167d - Fatal - **Results in Death**), Respiratory failure (167d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) |
| 2985 | click or scan EU-EC-10011413427 | | 2022-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Blood pressure abnormal (n/a - Fatal - **Results in Death**), Burning sensation (n/a - Fatal - **Results in Death**), Neuralgia (n/a - Fatal - **Results in Death**), Paresis (n/a - Fatal - **Results in Death**), Urticaria (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - .3mL - Intramuscular]) |
| 2986 | click or scan EU-EC-10011413136 | | 2022-01-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**, Disabling) | METHOTREXATE [METHOTREXATE] (I - n/a - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [HYDROXYCHLOROQUINE] (I - n/a - Not applicable - [n/a - n/a - n/a]), [IMMUNGLOBULIN] (I - n/a - Not applicable - [n/a - n/a - n/a]), [PREDNISONE] (I - n/a - Not applicable - [n/a - n/a - n/a]) |
| 2987 | click or scan EU-EC-10011411028 | | 2022-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2988** | click or scan EU-EC-10011411847 | | 2022-01-27 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2989** | click or scan EU-EC-10011409213 | | 2022-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Chills (15d - Recovered/Resolved - ), Cough (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Fatigue (16d - Unknown - ), Hypophagia (n/a - Fatal - **Results in Death**, Life Threatening), Hypothermia (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**), Nausea (16d - Recovered/Resolved - ), Pain (15d - Fatal - **Results in Death**), Pyrexia (15d - Recovered/Resolved - ), Vomiting (16d - Recovered/Resolved - ), Yellow skin (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **2990** | click or scan EU-EC-10011408378 | | 2022-01-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product use issue (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [INFLUENZA VIRUS] (S - Immunisation - Not applicable - [1d - n/a - n/a]) |
| **2991** | click or scan EU-EC-10011408374 | | 2022-01-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Chest pain (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Illness (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2992** | click or scan EU-EC-10011408252 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atrioventricular block first degree (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2993** | click or scan EU-EC-10011407939 | | 2022-01-27 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Hypersensitivity (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2994** | click or scan EU-EC-10011407682 | | 2022-01-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **2995** | click or scan EU-EC-10011407155 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **2996** | click or scan EU-EC-10011407146 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2997** | click or scan EU-EC-10011407143 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]), RONAPREVE [CASIRIVIMAB, IMDEVIMAB] (S - COVID-19 prophylaxis - n/a - [n/a - 600mg - Subcutaneous]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 2998 | click or scan EU-EC-10011407140 | | 2022-01-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 2999 | click or scan EU-EC-10011407111 | | 2022-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [D,L-LYSINE ACETYLSALICYLATE] (S - Cardiovascular event prophylaxis - Drug withdrawn - [n/a - 1 {DF} - Oral]) |
| 3000 | click or scan EU-EC-10011407110 | | 2022-01-27 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3001 | click or scan EU-EC-10011407053 | | 2022-01-27 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3002 | click or scan EU-EC-10011406906 | | 2022-01-27 | Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3003 | click or scan EU-EC-10011406719 | | 2022-01-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 3004 | click or scan EU-EC-10011406685 | | 2022-01-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3005 | click or scan EU-EC-10011406681 | | 2022-01-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3006 | click or scan EU-EC-10011406660 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3007 | click or scan EU-EC-10011406659 | | 2022-01-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3008 | click or scan EU-EC-10011406032 | | 2022-01-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3009 | click or scan EU-EC-10011405985 | | 2022-01-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3010 | click or scan EU-EC-10011405712 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3011 | click or scan EU-EC-10011405676 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3012 | click or scan EU-EC-10011405574 | | 2022-01-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3013 | click or scan EU-EC-10011405200 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3014 | click or scan EU-EC-10011405125 | | 2022-01-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dermatomyositis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1 d - n/a - Intramuscular]), [HYDROXYCHLOROQUINE] (I - n/a - n/a - [n/a - n/a - n/a]), [IMMUNGLOBULIN] (I - n/a - n/a - [n/a - n/a - n/a]), [METHOTREXATE] (I - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (I - n/a - n/a - [n/a - n/a - n/a]) |
| 3015 | click or scan EU-EC-10011404896 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1 d - n/a - Intramuscular]) |
| 3016 | click or scan EU-EC-10011404699 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3017 | click or scan EU-EC-10011404206 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3018 | click or scan EU-EC-10011403959 | | 2022-01-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3019 | click or scan EU-EC-10011403701 | | 2022-01-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3020 | click or scan EU-EC-10011403470 | | 2022-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Poor quality sleep (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 3021 | click or scan EU-EC-10011403268 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 3022 | click or scan EU-EC-10011402682 | | 2022-01-27 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Adrenal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Akathisia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multisystem inflammatory syndrome in adults (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Poor peripheral circulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal haematoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Skin discolouration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3023 | click or scan EU-EC-10011401082 | | 2022-01-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain neoplasm (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3024 | click or scan EU-EC-10011401013 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthma (6390min - Fatal - **Results in Death**), COVID-19 (5d - Fatal - **Results in Death**), Cough (108h - Fatal - **Results in Death**), Dyspnoea (101h - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]), [SARS-COV-2, STRAIN CZ02, PRODUCED IN VERO CELLS, INACTIVATED] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3025 | click or scan EU-EC-10011400713 | | 2022-01-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3026 | click or scan EU-EC-10011400710 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3027 | click or scan EU-EC-10011400613 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3028 | click or scan EU-EC-10011400438 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3029 | click or scan EU-EC-10011400213 | | 2022-01-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Ruptured cerebral aneurysm (2d - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3030 | click or scan EU-EC-10011399863 | | 2022-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3031 | click or scan EU-EC-10011399270 | | 2022-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Oxygen saturation decreased (30d - Fatal - **Results in Death**), Pyrexia (30d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3032 | click or scan EU-EC-10011397661 | | 2022-01-26 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3033 | click or scan EU-EC-10011396907 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary fibrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - Unknown - [n/a - n/a - Unknown]), ELIQUIS [APIXABAN] (S - Cerebrovascular accident prophylaxis - Unknown - [n/a - n/a - Unknown]) |
| 3034 | click or scan EU-EC-10011396214 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3035 | click or scan EU-EC-10011396186 | | 2022-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (2d - Fatal - **Results in Death**), Petit mal epilepsy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [11d - n/a - n/a - More in ICSR]) |
| 3036 | click or scan EU-EC-10011395871 | | 2022-01-26 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Abortion spontaneous (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3037 | click or scan EU-EC-10011395535 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3038 | click or scan EU-EC-10011394979 | | 2022-01-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3039 | click or scan EU-EC-10011394553 | | 2022-01-26 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3040 | click or scan EU-EC-10011393947 | | 2022-01-26 | Healthcare Professional | EEA | 18-64 Years | Male | Completed suicide (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3041 | click or scan EU-EC-10011393696 | | 2022-01-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3042 | click or scan EU-EC-10011393613 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3043 | click or scan EU-EC-10011393569 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Inflammation (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Pulmonary microemboli (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3044 | click or scan EU-EC-10011393148 | | 2022-01-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3045 | click or scan EU-EC-10011392994 | | 2022-01-26 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3046 | click or scan EU-EC-10011392978 | | 2022-01-26 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 3047 | click or scan EU-EC-10011392950 | | 2022-01-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3048 | click or scan EU-EC-10011392857 | | 2022-01-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3049 | click or scan EU-EC-10011392785 | | 2022-01-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - ), Haemoptysis (n/a - Unknown - ), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3050 | click or scan EU-EC-10011392662 | | 2022-01-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arteritis coronary (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3051 | click or scan EU-EC-10011391860 | | 2022-01-26 | Healthcare Professional | Non EEA | Not Specified | Female | Coarctation of the aorta (n/a - Unknown - Congenital Anomaly), Double inlet left ventricle (n/a - Fatal - **Results in Death**, Congenital Anomaly), Heart disease congenital (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**), Ventricular septal defect (n/a - Unknown - Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 3052 | click or scan EU-EC-10011391835 | | 2022-01-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Carotid artery stenosis (n/a - Fatal - **Results in Death**), Gait inability (n/a - Unknown - Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Sitting disability (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3053 | click or scan EU-EC-10011391828 | | 2022-01-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hip fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pancreatitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3054 | click or scan EU-EC-10011391591 | | 2022-01-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Intracardiac thrombus (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3055 | click or scan EU-EC-10011391409 | | 2022-01-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Hypotonia (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3056 | click or scan EU-EC-10011391408 | | 2022-01-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3057 | click or scan EU-EC-10011390980 | | 2022-01-26 | Healthcare Professional | EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3058 | click or scan EU-EC-10011390798 | | 2022-01-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3059 | click or scan EU-EC-10011389690 | | 2022-01-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3060 | click or scan EU-EC-10011389372 | | 2022-01-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3061 | click or scan EU-EC-10011389323 | | 2022-01-26 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3062 | click or scan EU-EC-10011388977 | | 2022-01-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Somnolence (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3063 | click or scan EU-EC-10011388952 | | 2022-01-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3064 | click or scan EU-EC-10011388950 | | 2022-01-26 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3065 | click or scan EU-EC-10011388947 | | 2022-01-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3066 | click or scan EU-EC-10011388943 | | 2022-01-26 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3067 | click or scan EU-EC-10011388917 | | 2022-01-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3068 | click or scan EU-EC-10011388914 | | 2022-01-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3069 | click or scan EU-EC-10011388628 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 3070 | click or scan EU-EC-10011388394 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Embolism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intravenous (not otherwise specified)]) |
| 3071 | click or scan EU-EC-10011388196 | | 2022-01-26 | Non Healthcare Professional | EEA | 18-64 Years | Female | Coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3072 | click or scan EU-EC-10011388152 | | 2022-01-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3073 | click or scan EU-EC-10011388070 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3074 | click or scan EU-EC-10011388008 | | 2022-01-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3075 | click or scan EU-EC-10011387885 | | 2022-01-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3076 | click or scan EU-EC-10011387883 | | 2022-01-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3077 | click or scan EU-EC-10011387589 | | 2022-01-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3078 | click or scan EU-EC-10011387235 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (42d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3079 | click or scan EU-EC-10011387234 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | Carotid artery occlusion (7d - Fatal - **Results in Death**), Cerebral artery occlusion (7d - Fatal - **Results in Death**), Ischaemic stroke (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| 3080 | click or scan EU-EC-10011387233 | | 2022-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (5d - Fatal - **Results in Death**), Hypoxic-ischaemic encephalopathy (5d - Fatal - **Results in Death**), Loss of consciousness (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| 3081 | click or scan EU-EC-10011387213 | | 2022-01-26 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5 {DF} - Intramuscular]) |
| 3082 | click or scan EU-EC-10011386293 | | 2022-01-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3083 | click or scan EU-EC-10011385495 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3084 | click or scan EU-EC-10011385006 | | 2022-01-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3085 | click or scan EU-EC-10011384681 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3086 | click or scan EU-EC-10011384367 |  | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atelectasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Continuous haemodiafiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Life support (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3087 | click or scan EU-EC-10011384213 |  | 2022-01-25 | Non Healthcare Professional | EEA | Not Specified | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 3088 | click or scan EU-EC-10011384019 |  | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3089 | click or scan EU-EC-10011383628 |  | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**), Hallucination (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3090 | click or scan EU-EC-10011383417 |  | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3091 | click or scan EU-EC-10011383368 |  | 2022-01-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Depression (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 3092 | click or scan EU-EC-10011383320 |  | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3093 | click or scan EU-EC-10011383182 |  | 2022-01-25 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3094 | click or scan EU-EC-10011382044 | | 2022-01-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 3095 | click or scan EU-EC-10011381999 | | 2022-01-25 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 3096 | click or scan EU-EC-10011381911 | | 2022-01-25 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 3097 | click or scan EU-EC-10011381910 | | 2022-01-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 3098 | click or scan EU-EC-10011381894 | | 2022-01-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abnormal loss of weight (n/a - Fatal - **Results in Death**), Asthenia (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 3099 | click or scan EU-EC-10011381885 | | 2022-01-25 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 3100 | click or scan EU-EC-10011381717 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3101 | click or scan EU-EC-10011381498 | | 2022-01-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Chest pain (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3102 | click or scan EU-EC-10011380804 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3103 | click or scan EU-EC-10011380665 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Atrioventricular block second degree (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Recovering/Resolving - Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3104 | click or scan EU-EC-10011380474 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3105 | click or scan EU-EC-10011379954 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3106 | click or scan EU-EC-10011379834 | | 2022-01-25 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3107 | click or scan EU-EC-10011379787 | | 2022-01-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3108 | click or scan EU-EC-10011379786 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Coma scale (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Electrocardiogram (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3109 | click or scan EU-EC-10011379776 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3110 | click or scan EU-EC-10011379729 | | 2022-01-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Balance disorder (n/a - Fatal - **Results in Death**), Cognitive disorder (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3111 | click or scan EU-EC-10011379098 | | 2022-01-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hepatic infarction (n/a - Fatal - **Results in Death**), Neoplasm malignant (n/a - Fatal - **Results in Death**), Splenic infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3112 | click or scan EU-EC-10011378533 | | 2022-01-25 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital brain damage (n/a - Fatal - **Results in Death**, Congenital Anomaly) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Transplacental]) |
| 3113 | click or scan EU-EC-10011377554 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3114 | click or scan EU-EC-10011377267 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3115 | click or scan EU-EC-10011377177 | | 2022-01-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3116 | click or scan EU-EC-10011376779 | | 2022-01-25 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 3117 | click or scan EU-EC-10011376667 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood lactic acid (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Troponin I (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), pH body fluid (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3118 | click or scan EU-EC-10011376666 | | 2022-01-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3119 | click or scan EU-EC-10011375921 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3120 | click or scan EU-EC-10011375809 | | 2022-01-25 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1{DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 3121 | click or scan EU-EC-10011375809 | | 2022-01-25 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1{DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 3122 | click or scan EU-EC-10011375491 | | 2022-01-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3123 | click or scan EU-EC-10011375487 | | 2022-01-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3124 | click or scan EU-EC-10011375485 | | 2022-01-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3125 | click or scan EU-EC-10011375452 | | 2022-01-25 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - **Results in Death**), Product administered to patient of inappropriate age (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3126 | click or scan EU-EC-10011375388 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3127 | click or scan EU-EC-10011374790 | | 2022-01-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3128 | click or scan EU-EC-10011374537 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3129 | click or scan EU-EC-10011374192 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3130 | click or scan EU-EC-10011374106 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypertension (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 3131 | click or scan EU-EC-10011374042 | | 2022-01-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3132 | click or scan EU-EC-10011373964 | | 2022-01-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3133 | click or scan EU-EC-10011373699 | | 2022-01-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 3134 | click or scan EU-EC-10011373317 | | 2022-01-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Artery dissection (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3135 | click or scan EU-EC-10011372543 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3136 | click or scan EU-EC-10011372536 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac procedure complication (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3137 | click or scan EU-EC-10011371350 | | 2022-01-24 | Healthcare Professional | EEA | 65-85 Years | Female | Hyperthermia malignant (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - Dose not changed - [n/a - n/a - Subcutaneous]) |
| 3138 | click or scan EU-EC-10011371224 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3139 | click or scan EU-EC-10011371175 | | 2022-01-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Dehydration (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3140 | click or scan EU-EC-10011371119 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening), Tenderness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3141 | click or scan EU-EC-10011370882 | | 2022-01-24 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal growth restriction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal heart rate abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 3142 | click or scan EU-EC-10011370840 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Alanine aminotransferase increased (n/a - Unknown - ), Aspartate aminotransferase increased (n/a - Unknown - ), Blood creatine phosphokinase MB increased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Blood phosphorus increased (n/a - Unknown - Other Medically Important Condition), Blood pressure increased (n/a - Unknown - ), Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Fibrin degradation products increased (n/a - Unknown - Other Medically Important Condition), Gamma-glutamyltransferase increased (n/a - Unknown - ), Lymphocyte count increased (n/a - Unknown - Other Medically Important Condition), Neutrophil count increased (n/a - Unknown - Other Medically Important Condition), Osmolar gap increased (n/a - Unknown - ), Protein total decreased (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ), White blood cell count increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3143 | click or scan EU-EC-10011370692 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3144 | click or scan EU-EC-10011370687 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3145 | click or scan EU-EC-10011370421 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Myalgia (n/a - Fatal - **Results in Death**, Life Threatening), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3146 | click or scan EU-EC-10011370420 |  | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3147 | click or scan EU-EC-10011370136 |  | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hallucination (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3148 | click or scan EU-EC-10011369916 |  | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3149 | click or scan EU-EC-10011369841 |  | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Hepatomegaly (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sinusitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3150 | click or scan EU-EC-10011369613 |  | 2022-01-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3151 | click or scan EU-EC-10011369613 |  | 2022-01-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3152 | click or scan EU-EC-10011369612 |  | 2022-01-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypersensitivity (n/a - Unknown - Caused/Prolonged Hospitalisation), Liver injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3153 | click or scan EU-EC-10011369505 |  | 2022-01-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3154 | click or scan EU-EC-10011369252 |  | 2022-01-24 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3155 | click or scan EU-EC-10011368881 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiomegaly (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Personality change (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3156 | click or scan EU-EC-10011368377 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Paraparesis (n/a - Fatal - **Results in Death**), Pyrexia (3d - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3157 | click or scan EU-EC-10011368307 | | 2022-01-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 3158 | click or scan EU-EC-10011368081 | | 2022-01-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .25mL - Unknown]) |
| 3159 | click or scan EU-EC-10011367681 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Rectal cancer (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3160 | click or scan EU-EC-10011367549 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3161 | click or scan EU-EC-10011367408 | | 2022-01-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3162 | click or scan EU-EC-10011367207 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3163 | click or scan EU-EC-10011367009 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [0mo - n/a - Intramuscular]) |
| 3164 | click or scan EU-EC-10011366792 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3165 | click or scan EU-EC-10011366601 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3166 | click or scan EU-EC-10011366464 | | 2022-01-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Recovering/Resolving - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - ), Wheezing (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3167 | click or scan EU-EC-10011366462 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain oedema (n/a - Unknown - Other Medically Important Condition), Lymph node haemorrhage (n/a - Unknown - ), Myocardial fibrosis (n/a - Unknown - ), Myocardial rupture (n/a - Unknown - Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3168 | click or scan EU-EC-10011366291 | | 2022-01-24 | Healthcare Professional | EEA | More than 85 Years | Male | Brain injury (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 3169 | click or scan EU-EC-10011366205 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3170 | click or scan EU-EC-10011366164 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3171 | click or scan EU-EC-10011366046 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3172 | click or scan EU-EC-10011366028 | | 2022-01-24 | Healthcare Professional | EEA | 65-85 Years | Female | Thrombosis (24d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3173 | click or scan EU-EC-10011365994 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fall (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 3174 | click or scan EU-EC-10011365433 | | 2022-01-24 | Healthcare Professional | EEA | More than 85 Years | Female | Peripheral artery stenosis (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3175 | click or scan EU-EC-10011365420 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3176 | click or scan EU-EC-10011365390 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Lung neoplasm malignant (n/a - Fatal - **Results in Death**), Metastases to central nervous system (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3177 | click or scan EU-EC-10011365386 | | 2022-01-24 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3178 | click or scan EU-EC-10011365292 | | 2022-01-24 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3179 | click or scan EU-EC-10011365287 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3180 | click or scan EU-EC-10011365064 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 3181 | click or scan EU-EC-10011364386 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Unknown - Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Electrocardiogram abnormal (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Paroxysmal arrhythmia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 3182 | click or scan EU-EC-10011363880 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3183 | click or scan EU-EC-10011363879 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3184 | click or scan EU-EC-10011363865 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3185 | click or scan EU-EC-10011363850 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3186 | click or scan EU-EC-10011363833 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3187 | click or scan EU-EC-10011363824 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Venous operation (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3188 | click or scan EU-EC-10011363815 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 5{DF} - n/a]) |
| 3189 | click or scan EU-EC-10011363814 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Influenza like illness (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3190 | click or scan EU-EC-10011363800 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 3191 | click or scan EU-EC-10011363783 | | 2022-01-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3192 | click or scan EU-EC-10011363771 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3193 | click or scan EU-EC-10011363747 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Quadriplegia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**), Skin lesion (n/a - Fatal - **Results in Death**), Skin weeping (n/a - Fatal - **Results in Death**), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3194 | click or scan EU-EC-10011363636 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3195 | click or scan EU-EC-10011363609 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diabetes mellitus (n/a - Fatal - **Results in Death**), Essential hypertension (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3196 | click or scan EU-EC-10011363500 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Headache (6d - Fatal - **Results in Death**), Influenza like illness (6d - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3197 | click or scan EU-EC-10011363080 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3198 | click or scan EU-EC-10011362976 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3199 | click or scan EU-EC-10011362749 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3200 | click or scan EU-EC-10011362746 | | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3201 | click or scan EU-EC-10011362425 | | 2022-01-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (49d - Fatal - **Results in Death**), Cough (49d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Dizziness (49d - Fatal - **Results in Death**), Labile hypertension (49d - Fatal - **Results in Death**), Malaise (49d - Fatal - **Results in Death**), Movement disorder (49d - Fatal - **Results in Death**), Myocardial infarction (0d - Fatal - **Results in Death**), Paraesthesia (49d - Fatal - **Results in Death**), Pyrexia (49d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| 3202 | click or scan EU-EC-10011362328 | | 2022-01-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3203 | click or scan EU-EC-10011362323 | | 2022-01-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3204 | click or scan EU-EC-10011362301 | | 2022-01-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3205 | click or scan EU-EC-10011362108 | | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3206 | click or scan EU-EC-10011362007 |  | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxic epidermal necrolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3207 | click or scan EU-EC-10011361957 |  | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac discomfort (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3208 | click or scan EU-EC-10011361749 |  | 2022-01-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood glucose increased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3209 | click or scan EU-EC-10011361670 |  | 2022-01-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3210 | click or scan EU-EC-10011361642 |  | 2022-01-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (4d - Fatal - **Results in Death**), Chills (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3211 | click or scan EU-EC-10011361437 |  | 2022-01-24 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3212 | click or scan EU-EC-10011361230 |  | 2022-01-24 | Non Healthcare Professional | EEA | Not Specified | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3213 | click or scan EU-EC-10011360496 |  | 2022-01-23 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3214 | click or scan EU-EC-10011360317 |  | 2022-01-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3215 | click or scan EU-EC-10011358451 |  | 2022-01-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3216 | click or scan EU-EC-10011358351 | | 2022-01-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (45d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3217 | click or scan EU-EC-10011355853 | | 2022-01-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aphthous ulcer (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3218 | click or scan EU-EC-10011355828 | | 2022-01-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3219 | click or scan EU-EC-10011355815 | | 2022-01-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Connective tissue disorder (88d - Fatal - **Results in Death**), Oxygen therapy (88d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3220 | click or scan EU-EC-10011355722 | | 2022-01-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3221 | click or scan EU-EC-10011353658 | | 2022-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - ), Dysgeusia (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine associated enhanced disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3222 | click or scan EU-EC-10011353390 | | 2022-01-21 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 immunisation (n/a - Unknown - **Results in Death**, Congenital Anomaly), Congenital cardiovascular anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Congenital central nervous system anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Recovered/Resolved - **Results in Death**, Congenital Anomaly), Hydronephrosis (n/a - Fatal - **Results in Death**, Congenital Anomaly) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| 3223 | click or scan EU-EC-10011353150 | | 2022-01-21 | Healthcare Professional | EEA | Not Specified | Not Specified | Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Umbilical cord thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 3224 | click or scan EU-EC-10011353031 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation), Sickle cell anaemia with crisis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Unknown - [n/a - n/a - Intramuscular]) |
| 3225 | click or scan EU-EC-10011353021 | | 2022-01-21 | Healthcare Professional | EEA | Not Specified | Female | Brain death (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Renal failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3226 | click or scan EU-EC-10011352981 |  | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**), Coma (n/a - Unknown - Life Threatening), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 3227 | click or scan EU-EC-10011352977 |  | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Splenic vein thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3228 | click or scan EU-EC-10011352897 |  | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3229 | click or scan EU-EC-10011352712 |  | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 3230 | click or scan EU-EC-10011351979 |  | 2022-01-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Intestinal obstruction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Nervousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Organ failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3231 | click or scan EU-EC-10011351965 |  | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3232 | click or scan EU-EC-10011351846 |  | 2022-01-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3233 | click or scan EU-EC-10011351779 |  | 2022-01-21 | Healthcare Professional | EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3234 | click or scan EU-EC-10011351403 |  | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3235 | click or scan EU-EC-10011351075 |  | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3236 | click or scan EU-EC-10011351007 | | 2022-01-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3237 | click or scan EU-EC-10011350867 | | 2022-01-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3238 | click or scan EU-EC-10011350823 | | 2022-01-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Brain abscess (n/a - Fatal - **Results in Death**), Liver injury (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3239 | click or scan EU-EC-10011350773 | | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3240 | click or scan EU-EC-10011350717 | | 2022-01-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Swelling (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3241 | click or scan EU-EC-10011350575 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 3242 | click or scan EU-EC-10011350458 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Pulseless electrical activity (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Ventricular fibrillation (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Wound haemorrhage (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 3243 | click or scan EU-EC-10011349691 | | 2022-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 3244 | click or scan EU-EC-10011349586 | | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 3245 | click or scan EU-EC-10011349513 | | 2022-01-21 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3246 | click or scan EU-EC-10011349501 | | 2022-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3247 | click or scan EU-EC-10011349382 | | 2022-01-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3248 | click or scan EU-EC-10011348963 | | 2022-01-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3249 | click or scan EU-EC-10011348938 | | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3250 | click or scan EU-EC-10011348876 | | 2022-01-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3251 | click or scan EU-EC-10011348371 | | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3252 | click or scan EU-EC-10011348357 | | 2022-01-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3253 | click or scan EU-EC-10011348354 | | 2022-01-21 | Non Healthcare Professional | EEA | More than 85 Years | Male | Back pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3254 | click or scan EU-EC-10011348344 | | 2022-01-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3255 | click or scan EU-EC-10011347164 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3256 | click or scan EU-EC-10011346556 | | 2022-01-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3257 | click or scan EU-EC-10011346554 |  | 2022-01-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3258 | click or scan EU-EC-10011346553 |  | 2022-01-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3259 | click or scan EU-EC-10011346545 |  | 2022-01-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3260 | click or scan EU-EC-10011346535 |  | 2022-01-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3261 | click or scan EU-EC-10011346450 |  | 2022-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3262 | click or scan EU-EC-10011345984 |  | 2022-01-21 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (4d - Fatal - **Results in Death**), COVID-19 (4d - Fatal - **Results in Death**), Death (4d - Fatal - **Results in Death**), Hypoxia (4d - Fatal - **Results in Death**), SARS-CoV-2 test positive (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3263 | click or scan EU-EC-10011345925 |  | 2022-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3264 | click or scan EU-EC-10011345818 |  | 2022-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Arteriosclerosis coronary artery (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Exostosis (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung infiltration (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal atrophy (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3265 | click or scan EU-EC-10011345720 |  | 2022-01-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3266 | click or scan EU-EC-10011345519 | | 2022-01-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic thrombosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Monoplegia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasopharyngitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3267 | click or scan EU-EC-10011345357 | | 2022-01-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3268 | click or scan EU-EC-10011345315 | | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3269 | click or scan EU-EC-10011345253 | | 2022-01-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 3270 | click or scan EU-EC-10011345228 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - ), Lip oedema (n/a - Fatal - **Results in Death**, Life Threatening), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Skin induration (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3271 | click or scan EU-EC-10011345182 | | 2022-01-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (10d - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (10d - Fatal - **Results in Death**, Other Medically Important Condition), Cough (10d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (10d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (10d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (10d - Fatal - **Results in Death**, Other Medically Important Condition), Rhinorrhoea (10d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3272 | click or scan EU-EC-10011345121 | | 2022-01-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3273 | click or scan EU-EC-10011345092 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3274 | click or scan EU-EC-10011345091 | | 2022-01-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (2mo - Unknown - Life Threatening), Asthenia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dermatomyositis (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - ), Dyspnoea exertional (n/a - Unknown - ), Eye swelling (n/a - Unknown - ), Immobile (2mo - Unknown - ), Incorrect dose administered (n/a - Unknown - ), Incorrect route of product administration (n/a - Unknown - ), Motor dysfunction (n/a - Unknown - ), Muscular weakness (n/a - Unknown - Life Threatening), Myalgia (n/a - Unknown - ), Myopathy (n/a - Unknown - ), Myositis (n/a - Unknown - ), Post vaccination syndrome (2mo - Unknown - ), Rash erythematous (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Dose not changed - [53d - n/a - Intravenous (not otherwise specified)]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [23d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3275** | click or scan EU-EC-10011345068 | | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Male | Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3276** | click or scan EU-EC-10011345052 | | 2022-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **3277** | click or scan EU-EC-10011344674 | | 2022-01-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3278** | click or scan EU-EC-10011344638 | | 2022-01-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3279** | click or scan EU-EC-10011344356 | | 2022-01-21 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3280** | click or scan EU-EC-10011344229 | | 2022-01-21 | Non Healthcare Professional | EEA | Not Specified | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3281** | click or scan EU-EC-10011344208 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3282** | click or scan EU-EC-10011344117 | | 2022-01-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (4d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**), Gastrointestinal disorder (22d - Fatal - **Results in Death**, Other Medically Important Condition), Immune system disorder (33d - Fatal - **Results in Death**, Other Medically Important Condition), Neoplasm malignant (42d - Fatal - **Results in Death**, Other Medically Important Condition), Skin disorder (42d - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3283 | click or scan EU-EC-10011344069 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Carotid artery thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3284 | click or scan EU-EC-10011343670 | | 2022-01-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3285 | click or scan EU-EC-10011343514 | | 2022-01-21 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Stillbirth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| 3286 | click or scan EU-EC-10011343275 | | 2022-01-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3287 | click or scan EU-EC-10011342932 | | 2022-01-21 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Unknown - ), Myelitis transverse (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3288 | click or scan EU-EC-10011342586 | | 2022-01-21 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3289 | click or scan EU-EC-10011342001 | | 2022-01-21 | Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (31d - Fatal - **Results in Death**), Coagulopathy (31d - Fatal - **Results in Death**), Dysphagia (31d - Fatal - **Results in Death**), Fungal sepsis (31d - Fatal - **Results in Death**), Haemoglobinuria (31d - Fatal - **Results in Death**), Hemiparesis (31d - Fatal - **Results in Death**), Ischaemic stroke (31d - Fatal - **Results in Death**), Pancytopenia (31d - Fatal - **Results in Death**), Speech disorder (31d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3290 | click or scan EU-EC-10011341483 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion (n/a - Fatal - **Results in Death**, Life Threatening), Maternal exposure during pregnancy (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3291 | click or scan EU-EC-10011340498 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3292 | click or scan EU-EC-10011340339 | | 2022-01-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Depressed level of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Disorganised speech (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3293 | click or scan EU-EC-10011340214 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Female | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3294 | click or scan EU-EC-10011340103 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oral herpes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 3295 | click or scan EU-EC-10011339877 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Gait disturbance (n/a - Unknown - ), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3296 | click or scan EU-EC-10011339641 | | 2022-01-20 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Fatigue (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3297 | click or scan EU-EC-10011339605 | | 2022-01-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Diplegia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3298 | click or scan EU-EC-10011339007 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3299 | click or scan EU-EC-10011338898 | | 2022-01-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertensive crisis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3300 | click or scan EU-EC-10011338891 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3301 | click or scan EU-EC-10011338543 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3302 | click or scan EU-EC-10011338458 | | 2022-01-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3303 | click or scan EU-EC-10011338446 | | 2022-01-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3304 | click or scan EU-EC-10011337803 | | 2022-01-20 | Non Healthcare Professional | EEA | Not Specified | Female | Arterial rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3305 | click or scan EU-EC-10011337798 | | 2022-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Anaemia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Blood iron increased (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Chronic obstructive pulmonary disease (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Mean cell volume increased (n/a - Unknown - ), Monocyte count increased (n/a - Unknown - ), Pain (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Productive cough (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Red blood cell sedimentation rate increased (n/a - Unknown - ), Red cell distribution width increased (n/a - Unknown - ), Renal impairment (n/a - Fatal - **Results in Death**), Reticulocyte count decreased (n/a - Unknown - ), Serum ferritin increased (n/a - Unknown - ), Swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Underweight (n/a - Unknown - ), White blood cell count decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3306 | click or scan EU-EC-10011337624 | | 2022-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3307 | click or scan EU-EC-10011337624 | | 2022-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3308 | click or scan EU-EC-10011337622 | | 2022-01-20 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Transplacental]) |
| 3309 | click or scan EU-EC-10011337410 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3310 | click or scan EU-EC-10011337385 | | 2022-01-20 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 3311 | click or scan EU-EC-10011337370 | | 2022-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3312 | click or scan EU-EC-10011337366 | | 2022-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3313 | click or scan EU-EC-10011337358 | | 2022-01-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3314 | click or scan EU-EC-10011337327 | | 2022-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac discomfort (n/a - Fatal - **Results in Death**), Gallbladder enlargement (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3315 | click or scan EU-EC-10011336832 | | 2022-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atypical mycobacterial infection (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neutrophil count increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3316 | click or scan EU-EC-10011336343 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoperitoneum (3d - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemia (3d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Portosplenomesenteric venous thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenomegaly (3d - Fatal - **Results in Death**), Thrombocytopenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3317 | click or scan EU-EC-10011336024 | | 2022-01-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3318 | click or scan EU-EC-10011335772 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3319 | click or scan EU-EC-10011335728 | | 2022-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (30min - Fatal - **Results in Death**), Mouth haemorrhage (30min - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3320 | click or scan EU-EC-10011335378 | | 2022-01-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Burning sensation (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Choking (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Limb discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3321 | click or scan EU-EC-10011335339 | | 2022-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cyanosis (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3322 | click or scan EU-EC-10011335296 | | 2022-01-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3323 | click or scan EU-EC-10011334975 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 3324 | click or scan EU-EC-10011334314 | | 2022-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccine induced antibody absent (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3325 | click or scan EU-EC-10011334148 | | 2022-01-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Not Recovered/Not Resolved - ), Cough (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Pneumonia (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a - n/a - Unknown]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Prophylaxis - Not applicable - [n/a - n/a - Unknown]) |
| 3326 | click or scan EU-EC-10011333277 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Female | Brain hypoxia (n/a - Fatal - **Results in Death**), Brain injury (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**), Type 1 diabetes mellitus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3327 | click or scan EU-EC-10011333112 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection rupture (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3328 | click or scan EU-EC-10011333066 | | 2022-01-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Disabling), Face and mouth X-ray (n/a - Fatal - **Results in Death**, Disabling), Feeling hot (n/a - Fatal - **Results in Death**, Disabling), Immunisation (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 3329 | click or scan EU-EC-10011332770 | | 2022-01-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3330 | click or scan EU-EC-10011332579 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1 d - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (0 d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (1 d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1 d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3331 | click or scan EU-EC-10011332488 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Female | Arterial thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral artery occlusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral artery thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral ischaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Renal infarct (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Superior sagittal sinus thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Transverse sinus thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3332 | click or scan EU-EC-10011332370 | | 2022-01-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (10 d - Recovered/Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (10 d - Recovered/Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (10 d - Recovered/Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3333 | click or scan EU-EC-10011332313 | | 2022-01-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Empyema (19 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3334 | click or scan EU-EC-10011332274 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (1 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (1 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3335 | click or scan EU-EC-10011331819 | | 2022-01-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3336 | click or scan EU-EC-10011331814 | | 2022-01-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3337 | click or scan EU-EC-10011331809 | | 2022-01-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3338 | click or scan EU-EC-10011331808 | | 2022-01-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3339 | click or scan EU-EC-10011331785 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3340 | click or scan EU-EC-10011331782 | | 2022-01-20 | Healthcare Professional | EEA | Not Specified | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3341 | click or scan EU-EC-10011331573 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Acute coronary syndrome (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3342 | click or scan EU-EC-10011331555 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3343 | click or scan EU-EC-10011330445 | | 2022-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3344 | click or scan EU-EC-10011330330 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3345 | click or scan EU-EC-10011329681 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac hypertrophy (0d - Fatal - **Results in Death**), Chest pain (4d - Recovered/Resolved - ), Coronary artery disease (0d - Fatal - **Results in Death**), Dyspnoea (4d - Recovered/Resolved - ), Headache (4d - Recovered/Resolved - ), Myalgia (4d - Recovered/Resolved - ), Myocardial fibrosis (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3346 | click or scan EU-EC-10011329581 | | 2022-01-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3347 | click or scan EU-EC-10011329025 | | 2022-01-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 3348 | click or scan EU-EC-10011327773 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3349 | click or scan EU-EC-10011325001 | | 2022-01-20 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cytogenetic abnormality (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Foetal death (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly), Foetal growth restriction (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 3350 | click or scan EU-EC-10011324946 | | 2022-01-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3351 | click or scan EU-EC-10011324815 | | 2022-01-20 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Abortion spontaneous (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Congenital anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Transplacental]) |
| 3352 | click or scan EU-EC-10011324805 | | 2022-01-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Hydrops foetalis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure timing unspecified (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 3353 | click or scan EU-EC-10011324258 | | 2022-01-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Bell's palsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism venous (81d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Restless legs syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3354 | click or scan EU-EC-10011324193 | | 2022-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3355 | click or scan EU-EC-10011324128 | | 2022-01-20 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3356 | click or scan EU-EC-10011322597 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ill-defined disorder (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3357 | click or scan EU-EC-10011322314 | | 2022-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - Life Threatening), Local reaction (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3358 | click or scan EU-EC-10011322292 | | 2022-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3359 | click or scan EU-EC-10011321878 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3360 | click or scan EU-EC-10011321848 | | 2022-01-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3361 | click or scan EU-EC-10011321716 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (2d - Fatal - **Results in Death**), SARS-CoV-2 test positive (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3362 | click or scan EU-EC-10011321223 | | 2022-01-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3363 | click or scan EU-EC-10011320643 | | 2022-01-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmic storm (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3364 | click or scan EU-EC-10011320642 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (11d - Fatal - **Results in Death**), Depressed level of consciousness (11d - Fatal - **Results in Death**), Ischaemia (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3365 | click or scan EU-EC-10011320640 | | 2022-01-20 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**), Pulmonary oedema (1d - Fatal - **Results in Death**), Respiratory failure (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 3366 | click or scan EU-EC-10011320639 | | 2022-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (9d - Fatal - **Results in Death**), Groin pain (9d - Fatal - **Results in Death**), Loss of consciousness (9d - Fatal - **Results in Death**), Pain (9d - Fatal - **Results in Death**), Testicular pain (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3367 | click or scan EU-EC-10011320637 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (1d - Fatal - **Results in Death**), Hyperglycaemia (1d - Fatal - **Results in Death**), Hyperpyrexia (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3368 | click or scan EU-EC-10011320633 | | 2022-01-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Fatal - **Results in Death**), Retching (n/a - Fatal - **Results in Death**), Urinary retention (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 3369 | click or scan EU-EC-10011320631 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3370 | click or scan EU-EC-10011320625 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory disorder (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 3371 | click or scan EU-EC-10011320615 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Male | Intraventricular haemorrhage (4d - Fatal - **Results in Death**), Vertigo (4d - Fatal - **Results in Death**), Vomiting (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3372 | click or scan EU-EC-10011320598 | | 2022-01-20 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3373 | click or scan EU-EC-10011319403 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pain (n/a - Recovering/Resolving - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3374 | click or scan EU-EC-10011319246 | | 2022-01-19 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3375 | click or scan EU-EC-10011317936 | | 2022-01-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 3376 | click or scan EU-EC-10011316799 | | 2022-01-19 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 3377 | click or scan EU-EC-10011316701 | | 2022-01-19 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3378 | click or scan EU-EC-10011316597 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 3379 | click or scan EU-EC-10011316553 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3380 | click or scan EU-EC-10011316523 | | 2022-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3381 | click or scan EU-EC-10011316520 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac discomfort (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3382 | click or scan EU-EC-10011316489 | | 2022-01-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Candida infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac disorder (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Immunisation (n/a - Unknown - ), Liver injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**), Severe acute respiratory syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Staphylococcal infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3383 | click or scan EU-EC-10011316153 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3384 | click or scan EU-EC-10011315974 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Leukaemia (38d - Fatal - **Results in Death**), Lithiasis (38d - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3385 | click or scan EU-EC-10011315842 | | 2022-01-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3386 | click or scan EU-EC-10011315531 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3387 | click or scan EU-EC-10011315361 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3388 | click or scan EU-EC-10011315344 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Hypersensitivity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3389 | click or scan EU-EC-10011315338 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tracheal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3390 | click or scan EU-EC-10011315312 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3391 | click or scan EU-EC-10011314453 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3392 | click or scan EU-EC-10011314389 | | 2022-01-19 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3393 | click or scan EU-EC-10011314241 | | 2022-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug interaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), [HEPARIN, HEPARIN SODIUM] (S - Product used for unknown indication - Drug withdrawn - [n/a - n/a - n/a]) |
| 3394 | click or scan EU-EC-10011314115 | | 2022-01-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Condition aggravated (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysphagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mobility decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Motor neurone disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3395 | click or scan EU-EC-10011313824 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Head injury (n/a - Unknown - Other Medically Important Condition), Skull fracture (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3396 | click or scan EU-EC-10011313789 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .03mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3397 | click or scan EU-EC-10011312910 | | 2022-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Application site pain (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3398 | click or scan EU-EC-10011312096 | | 2022-01-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3399 | click or scan EU-EC-10011312014 | | 2022-01-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3400 | click or scan EU-EC-10011311753 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neck pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3401 | click or scan EU-EC-10011311577 | | 2022-01-19 | Healthcare Professional | Non EEA | Not Specified | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3402 | click or scan EU-EC-10011311522 | | 2022-01-19 | Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]) |
| 3403 | click or scan EU-EC-10011311315 | | 2022-01-19 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3404 | click or scan EU-EC-10011311271 | | 2022-01-19 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3405 | click or scan EU-EC-10011311118 | | 2022-01-19 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Muscular weakness (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3406 | click or scan EU-EC-10011311101 | | 2022-01-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3407 | click or scan EU-EC-10011311099 | | 2022-01-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3408 | click or scan EU-EC-10011311097 | | 2022-01-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3409 | click or scan EU-EC-10011311074 | | 2022-01-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3410 | click or scan EU-EC-10011310408 | | 2022-01-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Disabling), Chills (n/a - Fatal - **Results in Death**, Disabling), Death (n/a - Fatal - **Results in Death**), Extensive swelling of vaccinated limb (n/a - Fatal - **Results in Death**, Disabling), Fatigue (n/a - Fatal - **Results in Death**, Disabling), Feeling cold (n/a - Fatal - **Results in Death**, Disabling), Injection site induration (n/a - Fatal - **Results in Death**, Disabling), Injection site movement impairment (n/a - Fatal - **Results in Death**, Disabling), Injection site pain (n/a - Fatal - **Results in Death**, Disabling), Injection site reaction (n/a - Fatal - **Results in Death**, Disabling), Limb immobilisation (n/a - Fatal - **Results in Death**, Disabling), Lymphoma (n/a - Fatal - **Results in Death**, Disabling), Malaise (n/a - Fatal - **Results in Death**, Disabling), Myalgia (n/a - Fatal - **Results in Death**, Disabling), Plasma cell myeloma recurrent (n/a - Fatal - **Results in Death**, Disabling), Pyrexia (n/a - Fatal - **Results in Death**, Disabling), Skin fissures (n/a - Fatal - **Results in Death**, Disabling), Tinnitus (n/a - Fatal - **Results in Death**, Disabling) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3411 | click or scan EU-EC-10011309953 | | 2022-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3412 | click or scan EU-EC-10011309944 | | 2022-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3413 | click or scan EU-EC-10011309773 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sneezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3414 | click or scan EU-EC-10011309275 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3415 | click or scan EU-EC-10011308705 | | 2022-01-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3416 | click or scan EU-EC-10011308617 | | 2022-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3417 | click or scan EU-EC-10011308370 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Coma (n/a - Fatal - **Results in Death**), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**), Discomfort (n/a - Unknown - ), Generalised oedema (n/a - Fatal - **Results in Death**), Goitre (n/a - Fatal - **Results in Death**), Hepatic fibrosis (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3418 | click or scan EU-EC-10011308188 | | 2022-01-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3419 | click or scan EU-EC-10011308183 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3420 | click or scan EU-EC-10011308177 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3421 | click or scan EU-EC-10011308142 | | 2022-01-19 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3422 | click or scan EU-EC-10011308105 | | 2022-01-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3423 | click or scan EU-EC-10011308090 | | 2022-01-19 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal vascular malperfusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| 3424 | click or scan EU-EC-10011308002 | | 2022-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3425 | click or scan EU-EC-10011307866 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3426 | click or scan EU-EC-10011307848 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Night sweats (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3427 | click or scan EU-EC-10011307827 | | 2022-01-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Injury (n/a - Unknown - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Unknown - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Vascular stent stenosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3428 | click or scan EU-EC-10011307189 | | 2022-01-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), FLUAD TETRA [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Influenza immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3429 | click or scan EU-EC-10011306165 | | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3430 | click or scan EU-EC-10011306036 | | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3431 | click or scan EU-EC-10011305815 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (5d - Fatal - **Results in Death**), Dyspnoea (5d - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3432 | click or scan EU-EC-10011305741 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - ), General physical health deterioration (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Recovering/Resolving - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3433 | click or scan EU-EC-10011305678 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3434 | click or scan EU-EC-10011305549 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3435 | click or scan EU-EC-10011305438 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .25mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3436** | click or scan<br>EU-EC-10011305418 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **3437** | click or scan<br>EU-EC-10011305316 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN, A/BRISBANE/10/2007 (H3N2)-LIKE STRAIN, B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1) VREASS. X - 179 A, A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, NIB-104), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/NANCHANG/933/95 (H3N2), A/BAYERN/7/95 (H1N1) - LIKE STRAIN (A/JOHANNESBURG/82/96), B/BEIJING/184/93-LIKE STRAIN (B/HARBIN/7/94), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/CALIFORNIA/7/2004 (H3N2) - LIKE STRAIN (A/NEW YORK/55/2004 REASS. NYMC X-157), B/SHANGHAI/361/2002 - LIKE STRAIN (B/JIANGSU/10/2003), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/MOSCOW/10/99 (H3N2) - LIKE STRAIN (A/PANAMA/2007/99 REASS. RESVIR-17), B/SICHUAN/379/99-LIKE STRAIN (B/JOHANNESBURG/5/99), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)-DERIVED STRAIN USED NYMC X-181, B/BRISBANE/60/2008, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/PHUKET/3073/2013-LIKE VIRUS |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | (B/PHUKET/3073/2013, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN B, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1)V-LIKE VIRUS, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327), B/MASSACHUSETTS/2/2012 -DERIVED STRAIN USED (NYMC BX-51B), A/TEXAS/50/2012 (H3N2) â€“ DERIVED STRAIN USED (NYMC X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), B/MASSACHUSETTS/2/2012 -DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN A (H1N1), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN A (H3N2), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN B] (S - Influenza immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3438** | click or scan EU-EC-10011305260 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3439** | click or scan EU-EC-10011305196 | | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3440** | click or scan EU-EC-10011304872 | | 2022-01-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Unevaluable event (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3441 | click or scan EU-EC-10011304553 | | 2022-01-18 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .25mL - Intramuscular]) |
| 3442 | click or scan EU-EC-10011304370 | | 2022-01-18 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 3443 | click or scan EU-EC-10011304198 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bronchitis (n/a - Recovered/Resolved - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Urinary tract infection (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 3444 | click or scan EU-EC-10011304000 | | 2022-01-18 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3445 | click or scan EU-EC-10011303953 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 3446 | click or scan EU-EC-10011303797 | | 2022-01-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Balance disorder (n/a - Unknown - ), Cardiomegaly (n/a - Unknown - ), Chest discomfort (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Discomfort (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fall (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Limb discomfort (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Obesity (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Swelling (n/a - Unknown - ), Varicose vein (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3447 | click or scan EU-EC-10011303700 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3448 | click or scan EU-EC-10011303611 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3449 | click or scan EU-EC-10011303605 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3450 | click or scan EU-EC-10011303567 | | 2022-01-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3451 | click or scan EU-EC-10011303552 | | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Swelling face (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3452 | click or scan EU-EC-10011303354 | | 2022-01-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3453 | click or scan EU-EC-10011303237 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3454 | click or scan EU-EC-10011303050 | | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3455 | click or scan EU-EC-10011302447 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3456 | click or scan EU-EC-10011302441 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3457 | click or scan EU-EC-10011302439 | | 2022-01-18 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3458 | click or scan EU-EC-10011302310 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 3459 | click or scan EU-EC-10011302254 | | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3460 | click or scan EU-EC-10011302225 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3461 | click or scan EU-EC-10011302219 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3462 | click or scan EU-EC-10011302218 | | 2022-01-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3463 | click or scan EU-EC-10011302216 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3464 | click or scan EU-EC-10011302213 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3465 | click or scan EU-EC-10011302212 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Respiratory tract haemorrhage (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3466 | click or scan EU-EC-10011302206 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3467 | click or scan EU-EC-10011302191 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3468 | click or scan EU-EC-10011302186 | | 2022-01-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abdominal discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3469 | click or scan EU-EC-10011302184 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3470 | click or scan EU-EC-10011302180 |  | 2022-01-18 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3471 | click or scan EU-EC-10011302066 |  | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3472 | click or scan EU-EC-10011301978 |  | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3473 | click or scan EU-EC-10011301936 |  | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3474 | click or scan EU-EC-10011301783 |  | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3475 | click or scan EU-EC-10011301693 |  | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chronic inflammatory demyelinating polyradiculoneuropathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3476 | click or scan EU-EC-10011301370 |  | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 3477 | click or scan EU-EC-10011301245 |  | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Giant cell arteritis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Polymyalgia rheumatica (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (n/a - Unknown - ) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3478 | click or scan EU-EC-10011301036 |  | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3479 | click or scan EU-EC-10011301027 |  | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3480** | click or scan EU-EC-10011301026 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3481** | click or scan EU-EC-10011300382 | | 2022-01-18 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3482** | click or scan EU-EC-10011300363 | | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **3483** | click or scan EU-EC-10011300348 | | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (4d - Fatal - **Results in Death**), Malaise (4d - Fatal - **Results in Death**), Nausea (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**), Vomiting (4d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3484** | click or scan EU-EC-10011300347 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3485** | click or scan EU-EC-10011300342 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - Intramuscular]) |
| **3486** | click or scan EU-EC-10011300341 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3487** | click or scan EU-EC-10011300340 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3488** | click or scan EU-EC-10011300337 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anal incontinence (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Urinary incontinence (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3489** | click or scan EU-EC-10011300336 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anal incontinence (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Urinary incontinence (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3490 | click or scan EU-EC-10011300335 | | 2022-01-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Poikilocytosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pupils unequal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3491 | click or scan EU-EC-10011300333 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3492 | click or scan EU-EC-10011300332 | | 2022-01-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3493 | click or scan EU-EC-10011300331 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3494 | click or scan EU-EC-10011300330 | | 2022-01-18 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Tympanometry abnormal (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3495 | click or scan EU-EC-10011300327 | | 2022-01-18 | Non Healthcare Professional | EEA | Not Specified | Female | Breast cancer female (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3496 | click or scan EU-EC-10011299962 | | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3497 | click or scan EU-EC-10011299795 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cold sweat (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3498 | click or scan EU-EC-10011299655 | | 2022-01-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3499 | click or scan EU-EC-10011299645 | | 2022-01-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3500 | click or scan EU-EC-10011299276 | | 2022-01-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3501 | click or scan EU-EC-10011299257 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea exertional (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hot flush (n/a - Unknown - Other Medically Important Condition), Hypoglycaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertigo (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3502 | click or scan EU-EC-10011299188 | | 2022-01-18 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3503 | click or scan EU-EC-10011298859 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3504 | click or scan EU-EC-10011298172 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3505 | click or scan EU-EC-10011297773 | | 2022-01-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3506 | click or scan EU-EC-10011297753 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3507 | click or scan EU-EC-10011297403 | | 2022-01-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3508 | click or scan EU-EC-10011297379 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [0d - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3509 | click or scan EU-EC-10011296965 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coronary arterial stent insertion (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3510 | click or scan EU-EC-10011296922 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3511 | click or scan EU-EC-10011296896 | | 2022-01-18 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3512 | click or scan EU-EC-10011296429 | | 2022-01-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Immunisation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3513 | click or scan EU-EC-10011296351 | | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3514 | click or scan EU-EC-10011296348 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3515 | click or scan EU-EC-10011296172 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (4h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3516 | click or scan EU-EC-10011295930 | | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Epilepsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3517 | click or scan EU-EC-10011295791 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ageusia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3518 | click or scan EU-EC-10011295666 | | 2022-01-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (17d - Recovered/Resolved - ), Eating disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3519 | click or scan EU-EC-10011295468 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3520 | click or scan EU-EC-10011295276 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3521 | click or scan EU-EC-10011295256 | | 2022-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Vaccination site abscess (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3522 | click or scan EU-EC-10011295217 | | 2022-01-18 | Healthcare Professional | EEA | 18-64 Years | Male | Angioedema (n/a - Fatal - **Results in Death**), Hypersensitivity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3523 | click or scan EU-EC-10011294745 | | 2022-01-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3524 | click or scan EU-EC-10011294653 | | 2022-01-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomyopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3525 | click or scan EU-EC-10011294620 | | 2022-01-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3526 | click or scan EU-EC-10011294575 | | 2022-01-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3527 | click or scan EU-EC-10011293776 | | 2022-01-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3528 | click or scan EU-EC-10011293633 | | 2022-01-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3529 | click or scan EU-EC-10011291719 | | 2022-01-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3530 | click or scan EU-EC-10011291705 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3531 | click or scan EU-EC-10011291283 | | 2022-01-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3532 | click or scan EU-EC-10011290127 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypervolaemia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3533 | click or scan EU-EC-10011289988 | | 2022-01-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3534 | click or scan EU-EC-10011289988 | | 2022-01-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3535 | click or scan EU-EC-10011289332 | | 2022-01-17 | Healthcare Professional | EEA | 65-85 Years | Female | Capillary leak syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), PACLITAXEL [PACLITAXEL] (S - Invasive ductal breast carcinoma - Drug withdrawn - [86d - n/a - Intravenous drip]) |
| 3536 | click or scan EU-EC-10011289308 | | 2022-01-17 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3537 | click or scan EU-EC-10011289299 | | 2022-01-17 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3538 | click or scan EU-EC-10011289217 | | 2022-01-17 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [162d - 1 {DF} - Intramuscular]), VENCLYXTO 100 MG FILM COATED TABLETS [VENETOCLAX] (S - Acute myeloid leukaemia - Not applicable - [180d - 100mg - Oral]), VIDAZA POWDER FOR SUSPENSION FOR INJECTION [AZACITIDINE] (S - Acute myeloid leukaemia - Not applicable - [1029d - 37.5mg/m2 - Subcutaneous]) |
| 3539 | click or scan EU-EC-10011289168 | | 2022-01-17 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 3540 | click or scan EU-EC-10011289141 | | 2022-01-17 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3541 | click or scan EU-EC-10011289009 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3542 | click or scan EU-EC-10011288992 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Unknown - ), Interchange of vaccine products (1d - Recovered/Resolved - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Salivary hypersecretion (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3543 | click or scan EU-EC-10011288638 | | 2022-01-17 | Healthcare Professional | EEA | More than 85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Iliac artery rupture (n/a - Fatal - **Results in Death**), Peripheral artery aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3544 | click or scan EU-EC-10011288570 | | 2022-01-17 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3545 | click or scan EU-EC-10011288547 | | 2022-01-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3546 | click or scan EU-EC-10011288538 |  | 2022-01-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3547 | click or scan EU-EC-10011288489 |  | 2022-01-17 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3548 | click or scan EU-EC-10011288455 |  | 2022-01-17 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| 3549 | click or scan EU-EC-10011288336 |  | 2022-01-17 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3550 | click or scan EU-EC-10011288296 |  | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3551 | click or scan EU-EC-10011288268 |  | 2022-01-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 3552 | click or scan EU-EC-10011288006 |  | 2022-01-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3553 | click or scan EU-EC-10011287930 |  | 2022-01-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3554 | click or scan EU-EC-10011287909 |  | 2022-01-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (3d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Malaise (4d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3555 | click or scan EU-EC-10011287868 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Muscle spasms (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3556 | click or scan EU-EC-10011287230 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercoagulation (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral venous disease (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3557 | click or scan EU-EC-10011286908 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3558 | click or scan EU-EC-10011286826 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3559 | click or scan EU-EC-10011286801 | | 2022-01-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Syncope (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3560 | click or scan EU-EC-10011286743 | | 2022-01-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3561 | click or scan EU-EC-10011286652 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3562 | click or scan EU-EC-10011286626 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Unknown - Other Medically Important Condition), Choking sensation (n/a - Not Recovered/Not Resolved - ), Ear pain (n/a - Not Recovered/Not Resolved - ), Eye movement disorder (n/a - Not Recovered/Not Resolved - ), Feeding disorder (n/a - Not Recovered/Not Resolved - ), Gait inability (n/a - Not Recovered/Not Resolved - ), Muscle tightness (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [1d - n/a - Unknown]), XARELTO [RIVAROXABAN] (S - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]) |
| 3563 | click or scan EU-EC-10011286233 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3564 | click or scan EU-EC-10011285839 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3565 | click or scan EU-EC-10011285643 | | 2022-01-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovered/Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3566 | click or scan EU-EC-10011285498 | | 2022-01-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Embolic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Incontinence (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Palpitations (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3567 | click or scan EU-EC-10011285443 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Lung abscess (n/a - Fatal - **Results in Death**), Pulmonary tuberculosis (n/a - Fatal - **Results in Death**), Septic encephalopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3568 | click or scan EU-EC-10011284688 | | 2022-01-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3569 | click or scan EU-EC-10011284618 | | 2022-01-17 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3570 | click or scan EU-EC-10011284211 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3571 | click or scan EU-EC-10011284188 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3572 | click or scan EU-EC-10011283968 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3573 | click or scan EU-EC-10011283212 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3574 | click or scan EU-EC-10011283145 | | 2022-01-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3575 | click or scan EU-EC-10011282961 | | 2022-01-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3576 | click or scan EU-EC-10011282939 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (7d - Unknown - Other Medically Important Condition), Cerebrovascular accident (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Subcutaneous]) |
| 3577 | click or scan EU-EC-10011282925 | | 2022-01-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3578 | click or scan EU-EC-10011282824 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (4d - Unknown - ), Loss of personal independence in daily activities (4d - Unknown - ), Vomiting (4d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3579 | click or scan EU-EC-10011282795 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3580 | click or scan EU-EC-10011282783 | | 2022-01-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3581 | click or scan EU-EC-10011282754 | | 2022-01-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3582 | click or scan EU-EC-10011282606 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 3583 | click or scan EU-EC-10011282559 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung neoplasm (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 3584 | click or scan EU-EC-10011282510 | | 2022-01-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - Intramuscular]) |
| 3585 | click or scan EU-EC-10011282317 | | 2022-01-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3586 | click or scan EU-EC-10011281598 | | 2022-01-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5{DF} - Intramuscular]) |
| | | | | | | | | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), [A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN, A/BRISBANE/10/2007 (H3N2)-LIKE STRAIN, B/FLORIDA/4/2006-LIKE STRAIN, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/VICTORIA/361/2011 (H3N2)â€“DERIVED STRAIN USED (IVR-165), B/WISCONSIN/1/2010-LIKE STRAIN USED (NYMC BX-39) DERIVED FROM B/HUBEI-WUJIAGANG/158/2009, A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) |

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|---|---|---|---|---|---|---|---|---|---|
| **3587** | click or scan<br><br>EU-EC-10011281574 | | 2022-01-17 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperpyrexia (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**) | (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/MOSCOW/10/99 (H3N2) - LIKE STRAIN (A/PANAMA/2007/99 REASS. RESVIR-17), B/SICHUAN/379/99-LIKE STRAIN (B/JOHANNESBURG/5/99), A/SOUTH AUSTRALIA/55/2014 STRAIN, A/SWITZERLAND/9715293/2013 (H3N2) - LIKE STRAIN (A/SOUTH AUSTRALIA/55/2014, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, B/MASSACHUSETTS/02/2012, A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, A/VICTORIA/361/2011 (H3N2)â€“DERIVED STRAIN USED (IVR-165), B/WISCONSIN/1/2010-LIKE STRAIN USED (NYMC BX-39) DERIVED FROM B/HUBEI-WUJIAGANG/158/2009, A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, A/WISCONSIN/67/2005 (H3N2), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN, B/MALAYSIA/2506/2004 - LIKE STRAIN, B/BEIJING/184/93-LIKE STRAIN (B/YAMANASHI/166/98), A/SYDNEY/5/97 (H3N2)-LIKE STRAIN (A/SYDNEY/5/97 REASS. RESVIR 13), A/BEIJING/262/95 (H1N1) - LIKE STRAIN (A/BEIJING/262/95 REASS. X-127), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1), A/PERTH/16/2009 (H3N2) - LIKE STRAIN, B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009(H1N1)-LIKE STRAIN (NYMC X-179A), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NIB-65), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009(H1N1)-LIKE STRAIN (NYMC X-179A), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327), B/MASSACHUSETTS/02/2012, A/TEXAS/50/2012 (H3N2) â€“ DERIVED STRAIN USED (NYMC X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE STRAIN, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SOUTH AUSTRALIA/55/2014, IVR-175), A/CALIFORNIA/7/2009 (H1N1)PDM09 - |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List.(Drug Char - Indication PT - Action taken - Duration - Dose - Route)] |
|---|---|---|---|---|---|---|---|---|---|
| 3588 | click or scan EU-EC-10011281559 | | 2022-01-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3589 | click or scan EU-EC-10011281548 | | 2022-01-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arterial rupture (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 3590 | click or scan EU-EC-10011281520 | | 2022-01-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3591 | click or scan EU-EC-10011281319 | | 2022-01-16 | Healthcare Professional | EEA | Not Specified | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3592 | click or scan EU-EC-10011280443 | | 2022-01-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3593 | click or scan EU-EC-10011279535 | | 2022-01-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - .5mL - Intramuscular]) |
| 3594 | click or scan EU-EC-10011279076 | | 2022-01-15 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Multiple congenital abnormalities (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Coronavirus infection - Dose not changed - [n/a - n/a - Intramuscular]) |
| 3595 | click or scan EU-EC-10011278980 | | 2022-01-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (4d - Recovered/Resolved - ), Cardiomyopathy (n/a - Fatal - **Results in Death**), Somnolence (4d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3596 | click or scan EU-EC-10011278631 | | 2022-01-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3597 | click or scan EU-EC-10011278537 | | 2022-01-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiogenic shock (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 3598 | click or scan EU-EC-10011278536 | | 2022-01-15 | Healthcare Professional | EEA | More than 85 Years | Female | Carotid artery occlusion (5d - Fatal - **Results in Death**), Coma (5d - Fatal - **Results in Death**), Hemiparesis (5d - Fatal - **Results in Death**), Ischaemic stroke (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3599 | click or scan EU-EC-10011278471 | | 2022-01-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Oxygen saturation decreased (16d - Fatal - **Results in Death**), Respiratory fatigue (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3600 | click or scan EU-EC-10011278434 | | 2022-01-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (56d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3601 | click or scan EU-EC-10011277409 | | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3602 | click or scan EU-EC-10011277408 | | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (59d - Fatal - **Results in Death**), Cerebral infarction (59d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3603 | click or scan EU-EC-10011277359 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3604 | click or scan EU-EC-10011277343 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Male | Atonic seizures (31d - Fatal - **Results in Death**), Drop attacks (31d - Fatal - **Results in Death**), Pyrexia (31d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3605 | click or scan EU-EC-10011277342 | | 2022-01-14 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3606 | click or scan EU-EC-10011276379 | | 2022-01-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3607 | click or scan EU-EC-10011276301 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia klebsiella (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (S - n/a - Drug withdrawn - [60d - n/a - Oral]) |
| 3608 | click or scan EU-EC-10011276224 | | 2022-01-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3609 | click or scan EU-EC-10011276163 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3610 | click or scan EU-EC-10011276005 | | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 3611 | click or scan EU-EC-10011274698 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral artery occlusion (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 3612 | click or scan EU-EC-10011273091 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Unknown - ), Oral candidiasis (n/a - Fatal - **Results in Death**), Sepsis (0d - Fatal - **Results in Death**, Other Medically Important Condition), Stomatitis (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular - More in ICSR]) |
| 3613 | click or scan EU-EC-10011272412 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (9d - Fatal - **Results in Death**), Cerebrovascular accident (9d - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Intracranial aneurysm (n/a - Unknown - Other Medically Important Condition), Memory impairment (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 3614 | click or scan EU-EC-10011272182 | | 2022-01-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 50ug - Intramuscular]) |
| 3615 | click or scan EU-EC-10011272055 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiogram cerebral abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3616 | click or scan EU-EC-10011272055 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiogram cerebral abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3617 | click or scan EU-EC-10011272036 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3618 | click or scan EU-EC-10011271303 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3619 | click or scan EU-EC-10011271277 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3620 | click or scan EU-EC-10011271177 | | 2022-01-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3621 | click or scan EU-EC-10011270985 | | 2022-01-14 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3622 | click or scan EU-EC-10011270853 | | 2022-01-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3623 | click or scan EU-EC-10011270810 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3624 | click or scan EU-EC-10011270809 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3625 | click or scan EU-EC-10011270634 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3626 | click or scan EU-EC-10011270515 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3627 | click or scan EU-EC-10011270477 | | 2022-01-14 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 3628 | click or scan EU-EC-10011270466 | | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) |
| 3629 | click or scan EU-EC-10011270322 | | 2022-01-14 | Healthcare Professional | EEA | 18-64 Years | Female | Portal vein thrombosis (1mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3630 | click or scan EU-EC-10011270093 | | 2022-01-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3631 | click or scan EU-EC-10011269372 | | 2022-01-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac death (14d - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Eczema (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3632 | click or scan EU-EC-10011269369 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anosmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3633 | click or scan EU-EC-10011269300 | | 2022-01-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3634 | click or scan EU-EC-10011269164 | | 2022-01-14 | Healthcare Professional | EEA | Not Specified | Male | Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3635 | click or scan EU-EC-10011268134 | | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Constipation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary retention (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3636 | click or scan EU-EC-10011268131 | | 2022-01-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3637 | click or scan EU-EC-10011267451 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3638 | click or scan EU-EC-10011267078 | | 2022-01-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3639 | click or scan EU-EC-10011266546 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (5min - Fatal - **Results in Death**), Colon cancer stage III (5min - Fatal - **Results in Death**), Diarrhoea haemorrhagic (5min - Fatal - **Results in Death**), Haematochezia (5min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3640 | click or scan EU-EC-10011266155 | | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3641 | click or scan EU-EC-10011265448 | | 2022-01-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3642 | click or scan EU-EC-10011265165 | | 2022-01-14 | Healthcare Professional | EEA | 18-64 Years | Male | Hypotonia (2d - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3643 | click or scan EU-EC-10011265101 | | 2022-01-14 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3644 | click or scan EU-EC-10011265096 | | 2022-01-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3645 | click or scan EU-EC-10011265074 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic failure (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Shock haemorrhagic (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3646 | click or scan EU-EC-10011264660 | | 2022-01-14 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3647 | click or scan EU-EC-10011264566 |  | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3648 | click or scan EU-EC-10011264564 |  | 2022-01-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3649 | click or scan EU-EC-10011264481 |  | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 3650 | click or scan EU-EC-10011264473 |  | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3651 | click or scan EU-EC-10011264449 |  | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a]) |
| 3652 | click or scan EU-EC-10011264447 |  | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular]) |
| 3653 | click or scan EU-EC-10011264286 |  | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3654 | click or scan EU-EC-10011264276 |  | 2022-01-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Small cell lung cancer (184d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3655 | click or scan EU-EC-10011264200 |  | 2022-01-14 | Healthcare Professional | Non EEA | Not Specified | Female | Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Fatal - **Results in Death**), Migraine (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Petechiae (n/a - Unknown - ), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3656 | click or scan EU-EC-10011264196 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Back pain (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral thrombosis (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Musculoskeletal chest pain (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pulmonary thrombosis (0d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3657 | click or scan EU-EC-10011264069 | | 2022-01-14 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3658 | click or scan EU-EC-10011263955 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3659 | click or scan EU-EC-10011263899 | | 2022-01-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Cyanosis central (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypersensitivity (n/a - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Skin discolouration (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 3660 | click or scan EU-EC-10011263882 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3661 | click or scan EU-EC-10011263830 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3662 | click or scan EU-EC-10011263789 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3663 | click or scan EU-EC-10011263778 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3664 | click or scan EU-EC-10011263757 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Cough (n/a - Fatal - **Results in Death**, Life Threatening), Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3665 | click or scan EU-EC-10011263699 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Postoperative wound complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3666 | click or scan EU-EC-10011263670 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3667 | click or scan EU-EC-10011263667 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3668 | click or scan EU-EC-10011263666 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3669 | click or scan EU-EC-10011263653 | | 2022-01-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3670 | click or scan EU-EC-10011263576 | | 2022-01-14 | Healthcare Professional | EEA | 18-64 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3671 | click or scan EU-EC-10011263543 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3672 | click or scan EU-EC-10011263461 | | 2022-01-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3673 | click or scan EU-EC-10011263384 | | 2022-01-14 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3674 | click or scan EU-EC-10011263329 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3675 | click or scan EU-EC-10011263327 | | 2022-01-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Odynophagia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3676 | click or scan EU-EC-10011263303 | | 2022-01-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 3677 | click or scan EU-EC-10011262931 | | 2022-01-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3678 | click or scan EU-EC-10011262925 | | 2022-01-14 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperpyrexia (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Sopor (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3679 | click or scan EU-EC-10011261947 | | 2022-01-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Activated partial thromboplastin time shortened (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood albumin decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening), Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Inflammation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Pulmonary artery thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3680 | click or scan EU-EC-10011260561 | | 2022-01-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3681 | click or scan EU-EC-10011259960 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Fatal - **Results in Death**), Enteritis infectious (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Physical deconditioning (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - ), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3682 | click or scan EU-EC-10011259461 | | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3683 | click or scan EU-EC-10011259303 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disease recurrence (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypopnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3684 | click or scan EU-EC-10011258382 | | 2022-01-13 | Healthcare Professional | EEA | More than 85 Years | Not Specified | SARS-CoV-2 test positive (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3685 | click or scan EU-EC-10011257376 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 3686 | click or scan EU-EC-10011257365 | | 2022-01-13 | Healthcare Professional | EEA | 18-64 Years | Female | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .25mL - Intramuscular]) |
| 3687 | click or scan EU-EC-10011257159 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3688 | click or scan EU-EC-10011256986 | | 2022-01-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3689 | click or scan EU-EC-10011256802 | | 2022-01-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]) |
| 3690 | click or scan EU-EC-10011256528 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bundle branch block right (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Epigastric discomfort (n/a - Unknown - ), Malaise (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3691 | click or scan EU-EC-10011256524 | | 2022-01-13 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3692 | click or scan EU-EC-10011256499 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cold sweat (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Orthopnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3693 | click or scan EU-EC-10011256497 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Near drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3694 | click or scan EU-EC-10011256472 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3695 | click or scan EU-EC-10011256443 | | 2022-01-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse reaction (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 3696 | click or scan EU-EC-10011256424 | | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Malignant neoplasm progression (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 3697 | click or scan EU-EC-10011256360 | | 2022-01-13 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3698 | click or scan EU-EC-10011256327 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3699 | click or scan EU-EC-10011256323 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Immunosuppression (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lymphoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3700 | click or scan EU-EC-10011256322 | | 2022-01-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 3701 | click or scan EU-EC-10011256320 | | 2022-01-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3702 | click or scan EU-EC-10011256312 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Influenza (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3703 | click or scan EU-EC-10011256268 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3704 | click or scan EU-EC-10011256201 | | 2022-01-13 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (305d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3705 | click or scan EU-EC-10011256156 |  | 2022-01-13 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 3706 | click or scan EU-EC-10011256143 |  | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Male | Bone pain (128d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (115d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (128d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (128d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3707 | click or scan EU-EC-10011255621 |  | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3708 | click or scan EU-EC-10011255185 |  | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3709 | click or scan EU-EC-10011255067 |  | 2022-01-13 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3710 | click or scan EU-EC-10011255056 |  | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 3711 | click or scan EU-EC-10011255021 |  | 2022-01-13 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3712 | click or scan EU-EC-10011254674 |  | 2022-01-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3713 | click or scan EU-EC-10011254667 |  | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3714 | click or scan EU-EC-10011254535 |  | 2022-01-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3715 | click or scan EU-EC-10011254532 | | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (24d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pneumonia (24d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (24d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3716 | click or scan EU-EC-10011254511 | | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3717 | click or scan EU-EC-10011254410 | | 2022-01-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3718 | click or scan EU-EC-10011254407 | | 2022-01-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3719 | click or scan EU-EC-10011254405 | | 2022-01-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3720 | click or scan EU-EC-10011254102 | | 2022-01-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3721 | click or scan EU-EC-10011254097 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3722 | click or scan EU-EC-10011254093 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3723 | click or scan EU-EC-10011254088 | | 2022-01-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (14d - Recovered/Resolved With Sequelae - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 3724 | click or scan EU-EC-10011254025 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3725 | click or scan EU-EC-10011253672 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3726 | click or scan EU-EC-10011253105 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3727 | click or scan EU-EC-10011253101 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Circulatory collapse (n/a - Unknown - Life Threatening), Coagulopathy (n/a - Not Recovered/Not Resolved - Life Threatening), Headache (n/a - Unknown - Life Threatening), Loss of consciousness (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Life Threatening), Urinary retention (n/a - Unknown - Life Threatening), Vomiting (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3728 | click or scan EU-EC-10011252516 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3729 | click or scan EU-EC-10011251521 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Increased bronchial secretion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3730 | click or scan EU-EC-10011251494 | | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Oxygen saturation abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3731 | click or scan EU-EC-10011251157 | | 2022-01-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pancreatitis haemorrhagic (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3732 | click or scan EU-EC-10011251052 | | 2022-01-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3733 | click or scan EU-EC-10011251041 | | 2022-01-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3734 | click or scan EU-EC-10011250721 | | 2022-01-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Odynophagia (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3735 | click or scan EU-EC-10011250664 | | 2022-01-13 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3736 | click or scan EU-EC-10011250590 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3737 | click or scan EU-EC-10011250518 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3738 | click or scan EU-EC-10011250507 | | 2022-01-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dependence on respirator (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3739 | click or scan EU-EC-10011250387 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Accidental exposure to product (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3740 | click or scan EU-EC-10011250387 | | 2022-01-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Accidental exposure to product (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3741 | click or scan EU-EC-10011247664 | | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal distension (5d - Fatal - **Results in Death**), Asthenia (5d - Fatal - **Results in Death**), Cardiac arrest (5d - Fatal - **Results in Death**), Chest discomfort (5d - Fatal - **Results in Death**), Confusional state (5d - Fatal - **Results in Death**), Headache (5d - Fatal - **Results in Death**), Insomnia (5d - Fatal - **Results in Death**), Nausea (5d - Fatal - **Results in Death**), Vomiting (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .25mL - Intramuscular]) |
| 3742 | click or scan EU-EC-10011247661 | | 2022-01-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (1d - Fatal - **Results in Death**), Tremor (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3743 | click or scan EU-EC-10011247486 | | 2022-01-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Neoplasm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3744 | click or scan EU-EC-10011247212 | | 2022-01-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - n/a]) |
| 3745 | click or scan EU-EC-10011242254 | | 2022-01-12 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .25mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3746 | click or scan EU-EC-10011241942 |  | 2022-01-12 | Healthcare Professional | EEA | 18-64 Years | Female | Anaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Aortic thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea haemorrhagic (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intra-abdominal fluid collection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Lower gastrointestinal haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic infarction (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3747 | click or scan EU-EC-10011241695 |  | 2022-01-12 | Healthcare Professional | EEA | 65-85 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3748 | click or scan EU-EC-10011240864 |  | 2022-01-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriovenous malformation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysgeusia (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Traumatic intracranial haemorrhage (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 3749 | click or scan EU-EC-10011239886 |  | 2022-01-12 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3750 | click or scan EU-EC-10011239690 |  | 2022-01-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3751 | click or scan EU-EC-10011238424 |  | 2022-01-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3752 | click or scan EU-EC-10011238392 |  | 2022-01-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Ascites (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3753 | click or scan EU-EC-10011238302 |  | 2022-01-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3754 | click or scan EU-EC-10011238292 | | 2022-01-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3755 | click or scan EU-EC-10011237743 | | 2022-01-12 | Healthcare Professional | EEA | 65-85 Years | Female | Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3756 | click or scan EU-EC-10011237723 | | 2022-01-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - ), Presyncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3757 | click or scan EU-EC-10011237068 | | 2022-01-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pancreatic carcinoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3758 | click or scan EU-EC-10011236745 | | 2022-01-12 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3759 | click or scan EU-EC-10011236740 | | 2022-01-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3760 | click or scan EU-EC-10011236644 | | 2022-01-12 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3761 | click or scan EU-EC-10011236555 | | 2022-01-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - n/a]) |
| 3762 | click or scan EU-EC-10011234996 | | 2022-01-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac perforation (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Sinus node dysfunction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| 3763 | click or scan EU-EC-10011234331 | | 2022-01-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3764 | click or scan EU-EC-10011233972 | | 2022-01-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3765 | click or scan EU-EC-10011232076 | | 2022-01-12 | Non Healthcare Professional | EEA | Not Specified | Male | Injection site reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3766 | click or scan EU-EC-10011231431 | | 2022-01-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3767 | click or scan EU-EC-10011231389 | | 2022-01-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3768 | click or scan EU-EC-10011231209 | | 2022-01-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Catarrh (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haematoma (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3769 | click or scan EU-EC-10011230063 | | 2022-01-12 | Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal necrosis (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal ischaemia (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3770 | click or scan EU-EC-10011230026 | | 2022-01-12 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dehydration (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3771 | click or scan EU-EC-10011229907 | | 2022-01-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3772 | click or scan EU-EC-10011229768 | | 2022-01-12 | Healthcare Professional | Non EEA | Not Specified | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3773 | click or scan EU-EC-10011229558 | | 2022-01-12 | Healthcare Professional | EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3774 | click or scan EU-EC-10011229284 | | 2022-01-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Intestinal obstruction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3775 | click or scan EU-EC-10011229240 | | 2022-01-12 | Non Healthcare Professional | EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3776 | click or scan EU-EC-10011228800 | | 2022-01-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Hyperhidrosis (n/a - Unknown - **Results in Death**), Hypokinesia (n/a - Unknown - **Results in Death**), Limb discomfort (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3777 | click or scan EU-EC-10011227900 | | 2022-01-12 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Arrhythmia (n/a - Fatal - **Results in Death**), Balance disorder (n/a - Fatal - **Results in Death**), Blood disorder (n/a - Fatal - **Results in Death**), Capillary leak syndrome (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Neurological symptom (n/a - Fatal - **Results in Death**), Protein deficiency (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3778 | click or scan EU-EC-10011227794 | | 2022-01-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3779 | click or scan EU-EC-10011227489 | | 2022-01-12 | Healthcare Professional | Non EEA | Not Specified | Male | Aggression (n/a - Recovered/Resolved - Other Medically Important Condition), Agitation (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dementia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Social avoidant behaviour (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1mL - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3780 | click or scan EU-EC-10011226839 | | 2022-01-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Azotaemia (n/a - Fatal - **Results in Death**), Renal impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3781 | click or scan EU-EC-10011225368 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Immunisation (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3782 | click or scan EU-EC-10011225157 | | 2022-01-11 | Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhage intracranial (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3783 | click or scan EU-EC-10011224538 | | 2022-01-11 | Healthcare Professional | Non EEA | Not Specified | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [0y - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3784 | click or scan EU-EC-10011224536 |  | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Multisystem inflammatory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 3785 | click or scan EU-EC-10011224513 |  | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 3786 | click or scan EU-EC-10011224368 |  | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Diplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Partial seizures (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3787 | click or scan EU-EC-10011224100 |  | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3788 | click or scan EU-EC-10011224066 |  | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3789 | click or scan EU-EC-10011224039 |  | 2022-01-11 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3790 | click or scan EU-EC-10011223471 |  | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Anxiety (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Hepatic pain (n/a - Unknown - ), Hepatomegaly (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Hypertension (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3791 | click or scan EU-EC-10011222103 |  | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3792 | click or scan EU-EC-10011221862 | | 2022-01-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Antiphospholipid syndrome (n/a - Unknown - Other Medically Important Condition), Aphasia (n/a - Unknown - ), Ascites (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Dyslalia (n/a - Unknown - ), Eye movement disorder (n/a - Unknown - ), Haematochezia (n/a - Unknown - Other Medically Important Condition), Haemolytic uraemic syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Unknown - ), Haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Haemorrhagic diathesis (n/a - Unknown - Other Medically Important Condition), Heparin-induced thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Hyperventilation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Nephrotic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological symptom (n/a - Unknown - ), Paroxysmal nocturnal haemoglobinuria (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - ), Petechiae (n/a - Unknown - ), Platelet count decreased (n/a - Fatal - **Results in Death**), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Purpura (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3793 | click or scan EU-EC-10011221817 | | 2022-01-11 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 3794 | click or scan EU-EC-10011221800 | | 2022-01-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3795 | click or scan EU-EC-10011221749 | | 2022-01-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3796 | click or scan EU-EC-10011221730 | | 2022-01-11 | Healthcare Professional | EEA | 65-85 Years | Male | Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**) | CABOMETYX [CABOZANTINIB] (S - Hepatocellular carcinoma - Not applicable - [10d - 1 {DF} - Oral]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), NEXAVAR 200 MG FILM-COATED TABLETS [SORAFENIB, SORAFENIB TOSILATE] (S - Hepatocellular carcinoma - Not applicable - [15d - 1 {DF} - Oral]) |
| 3797 | click or scan EU-EC-10011221702 | | 2022-01-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 3798 | click or scan EU-EC-10011221687 | | 2022-01-11 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3799 | click or scan EU-EC-10011221671 | | 2022-01-11 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3800 | click or scan EU-EC-10011221530 | | 2022-01-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3801 | click or scan EU-EC-10011221345 | | 2022-01-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3802 | click or scan EU-EC-10011220943 | | 2022-01-11 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3803 | click or scan EU-EC-10011220597 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Other Medically Important Condition), Brain stem syndrome (n/a - Unknown - Other Medically Important Condition), Cerebellar infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eye movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - ), Gastric dilatation (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nervous system disorder (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3804 | click or scan EU-EC-10011220572 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3805 | click or scan EU-EC-10011220455 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - ), Lip oedema (n/a - Fatal - **Results in Death**, Life Threatening), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Skin induration (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3806 | click or scan EU-EC-10011220449 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3807 | click or scan EU-EC-10011220136 | | 2022-01-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 3808 | click or scan EU-EC-10011220099 | | 2022-01-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3809 | click or scan EU-EC-10011219920 | | 2022-01-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3810 | click or scan EU-EC-10011219067 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood gases (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea at rest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sedation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Serum ferritin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound Doppler normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Use of accessory respiratory muscles (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3811 | click or scan EU-EC-10011218817 | | 2022-01-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 3812 | click or scan EU-EC-10011218443 | | 2022-01-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Coagulopathy (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Hepatic artery occlusion (n/a - Unknown - Other Medically Important Condition), Hepatic enzyme increased (n/a - Unknown - Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3813 | click or scan EU-EC-10011218434 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Obesity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3814 | click or scan EU-EC-10011218422 | | 2022-01-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Embolism arterial (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3815** | click or scan EU-EC-10011218330 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Guillain-Barre syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypertension (n/a - Recovering/Resolving - ), Hypotonia (n/a - Recovering/Resolving - ), Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3816** | click or scan EU-EC-10011218320 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Odynophagia (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3817** | click or scan EU-EC-10011218150 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3818** | click or scan EU-EC-10011217781 | | 2022-01-11 | Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Areflexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation), Basal ganglia haemorrhage (n/a - Fatal - **Results in Death**), Coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypertensive crisis (n/a - Recovering/Resolving - Life Threatening), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3819** | click or scan EU-EC-10011217391 | | 2022-01-11 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Abortion (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Unknown - ) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3820** | click or scan EU-EC-10011216958 | | 2022-01-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3821** | click or scan EU-EC-10011216802 | | 2022-01-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3822** | click or scan EU-EC-10011216567 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Coronary artery stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3823** | click or scan EU-EC-10011216507 | | 2022-01-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3824 | click or scan EU-EC-10011216467 | | 2022-01-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Other Medically Important Condition), Dyspnoea (5wk - Unknown - Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertensive crisis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection (38d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Intensive care (5wk - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - ), Oral herpes (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Other Medically Important Condition), Quadriparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Radiculopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Staphylococcal infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Tracheobronchitis bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation), Tracheostomy malfunction (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3825 | click or scan EU-EC-10011216361 | | 2022-01-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), NOT AVAILABLE [MRNA 1273] (S - Immunisation - Unknown - [n/a - n/a - Unknown]) |
| 3826 | click or scan EU-EC-10011216333 | | 2022-01-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anaemia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (0d - Fatal - **Results in Death**), Cardiopulmonary failure (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Haematocrit decreased (n/a - Unknown - Other Medically Important Condition), Jugular vein thrombosis (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Necrosis (n/a - Unknown - Other Medically Important Condition), Neoplasm malignant (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3827 | click or scan EU-EC-10011216251 | | 2022-01-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Febrile convulsion (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 3828 | click or scan EU-EC-10011215290 | | 2022-01-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (1d - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Coronary artery occlusion (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Myocardial infarction (0d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3829 | click or scan EU-EC-10011215077 | | 2022-01-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hyponatraemia (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3830 | click or scan EU-EC-10011214641 | | 2022-01-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 3831 | click or scan EU-EC-10011213376 | | 2022-01-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3832 | click or scan EU-EC-10011213327 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 3833 | click or scan EU-EC-10011213071 | | 2022-01-10 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Splenic artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3834 | click or scan EU-EC-10011213063 | | 2022-01-10 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3835 | click or scan EU-EC-10011212977 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhagic stroke (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3836 | click or scan EU-EC-10011212895 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3837 | click or scan EU-EC-10011212541 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown]) |
| 3838 | click or scan EU-EC-10011212378 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Femur fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3839 | click or scan EU-EC-10011212341 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3840 | click or scan EU-EC-10011212332 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3841 | click or scan EU-EC-10011212146 | | 2022-01-10 | Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3842** | click or scan EU-EC-10011211990 | | 2022-01-10 | Healthcare Professional | Non EEA | Not Specified | Female | Coagulation disorder neonatal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disseminated intravascular coagulation in newborn (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage neonatal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hydrops foetalis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neonatal haemochromatosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **3843** | click or scan EU-EC-10011211980 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3844** | click or scan EU-EC-10011211821 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3845** | click or scan EU-EC-10011211815 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3846** | click or scan EU-EC-10011211323 | | 2022-01-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Immunology test (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3847** | click or scan EU-EC-10011211185 | | 2022-01-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mobility decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3848** | click or scan EU-EC-10011210629 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3849** | click or scan EU-EC-10011210416 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [CIPROFLOXACIN] (S - Urinary tract infection - n/a - [n/a - n/a - n/a]) |
| **3850** | click or scan EU-EC-10011210124 | | 2022-01-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Product use issue (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3851** | click or scan EU-EC-10011210063 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Carotid artery thrombosis (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral infarction (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Craniectomy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **3852** | click or scan EU-EC-10011209832 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Upper respiratory tract infection (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3853** | click or scan EU-EC-10011209636 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3854** | click or scan EU-EC-10011209122 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypoglycaemia (1d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3855** | click or scan EU-EC-10011209118 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Pneumonia adenoviral (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3856** | click or scan EU-EC-10011208884 | | 2022-01-10 | Healthcare Professional | EEA | 65-85 Years | Male | Apathy (n/a - Fatal - **Results in Death**), Bradyphrenia (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Fatigue (26d - Recovered/Resolved - ), Hypophagia (n/a - Fatal - **Results in Death**), Malaise (26d - Recovered/Resolved - ), Nausea (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **3857** | click or scan EU-EC-10011208873 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3858** | click or scan EU-EC-10011208853 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cerebral artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Drug interaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Unknown - Other Medically Important Condition), Quadriplegia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (I - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), ORENCIA [ABATACEPT] (I - Rheumatoid arthritis - Drug withdrawn - [8d - 125mg - Subcutaneous - More in ICSR]), [METHOTREXATE SODIUM] (I - Rheumatoid arthritis - Unknown - [n/a - 6mg - n/a]) |
| **3859** | click or scan EU-EC-10011208851 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (1wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3860 | click or scan EU-EC-10011208848 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Diabetes mellitus inadequate control (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 3861 | click or scan EU-EC-10011208841 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .25mL - Intramuscular]) |
| 3862 | click or scan EU-EC-10011208358 | | 2022-01-10 | Healthcare Professional | EEA | 65-85 Years | Female | Atrial flutter (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3863 | click or scan EU-EC-10011208013 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - .5mL - n/a]) |
| 3864 | click or scan EU-EC-10011208006 | | 2022-01-10 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3865 | click or scan EU-EC-10011206986 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3866 | click or scan EU-EC-10011206981 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal X-ray (n/a - Fatal - **Results in Death**), Abdominal pain upper (n/a - Fatal - **Results in Death**), Ageusia (n/a - Fatal - **Results in Death**), Alanine aminotransferase normal (n/a - Fatal - **Results in Death**), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Atelectasis (n/a - Fatal - **Results in Death**), Bilirubin conjugated increased (n/a - Fatal - **Results in Death**), Blood alkaline phosphatase increased (n/a - Fatal - **Results in Death**), Blood bilirubin increased (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Haematuria (n/a - Fatal - **Results in Death**), Lipase normal (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oesophageal spasm (n/a - Fatal - **Results in Death**), Troponin normal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - Unknown]) |
| 3867 | click or scan EU-EC-10011206589 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Female | Angiocentric lymphoma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chemotherapy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cutaneous lymphoma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphoproliferative disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nasal crusting (n/a - Not Recovered/Not Resolved - ), T-cell lymphoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3868 | click or scan EU-EC-10011206583 | | 2022-01-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Injection site erythema (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Oedema (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3869 | click or scan EU-EC-10011206577 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3870 | click or scan EU-EC-10011206573 | | 2022-01-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3871 | click or scan EU-EC-10011206572 | | 2022-01-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3872 | click or scan EU-EC-10011206560 | | 2022-01-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Ileus paralytic (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 3873 | click or scan EU-EC-10011206550 | | 2022-01-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Not Recovered/Not Resolved - ), Gastric haemorrhage (n/a - Fatal - **Results in Death**), Intestinal haemorrhage (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3874 | click or scan EU-EC-10011206542 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3875 | click or scan EU-EC-10011206538 | | 2022-01-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3876 | click or scan EU-EC-10011206528 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3877 | click or scan EU-EC-10011206524 | | 2022-01-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Jaundice (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3878 | click or scan EU-EC-10011206523 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3879 | click or scan EU-EC-10011206515 | | 2022-01-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3880** | click or scan EU-EC-10011206512 | | 2022-01-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chest tube removal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3881** | click or scan EU-EC-10011206511 | | 2022-01-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dementia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hallucination (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3882** | click or scan EU-EC-10011206228 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3883** | click or scan EU-EC-10011206227 | | 2022-01-10 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3884** | click or scan EU-EC-10011206226 | | 2022-01-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), NOT AVAILABLE [MRNA 1273] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| **3885** | click or scan EU-EC-10011205960 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Paresis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3886** | click or scan EU-EC-10011205956 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Carotid artery thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3887** | click or scan EU-EC-10011205949 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3888** | click or scan EU-EC-10011205689 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3889 | click or scan EU-EC-10011205367 | | 2022-01-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disturbance in attention (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - Not applicable - [1d - 1{DF} - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Prophylaxis - Not applicable - [1d - n/a - n/a]) |
| 3890 | click or scan EU-EC-10011205271 | | 2022-01-10 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3891 | click or scan EU-EC-10011205262 | | 2022-01-10 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3892 | click or scan EU-EC-10011205162 | | 2022-01-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 3893 | click or scan EU-EC-10011205152 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Medical induction of coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 3894 | click or scan EU-EC-10011205150 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3895 | click or scan EU-EC-10011204816 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 3896 | click or scan EU-EC-10011204687 | | 2022-01-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3897 | click or scan EU-EC-10011204611 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 3898 | click or scan EU-EC-10011204457 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**), Myocardial ischaemia (121d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3899 | click or scan EU-EC-10011204107 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness postural (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3900 | click or scan EU-EC-10011203911 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Staphylococcal infection (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3901 | click or scan EU-EC-10011203891 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**), Pulmonary fibrosis (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 3902 | click or scan EU-EC-10011203500 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebellar haemorrhage (12d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral thrombosis (12d - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (12d - Fatal - **Results in Death**), Headache (12d - Fatal - **Results in Death**), Jugular vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (12d - Fatal - **Results in Death**), Thrombocytopenia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vena cava thrombosis (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3903 | click or scan EU-EC-10011203474 | | 2022-01-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Somnolence (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site erythema (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), ELIQUIS [APIXABAN] (S - Deep vein thrombosis, Pulmonary embolism - Dose not changed - [n/a - 5mg - Oral]) |
| 3904 | click or scan EU-EC-10011203088 | | 2022-01-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cognitive disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3905 | click or scan EU-EC-10011202895 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3906 | click or scan EU-EC-10011202851 | | 2022-01-10 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3907 | click or scan EU-EC-10011202850 | | 2022-01-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3908 | click or scan EU-EC-10011202830 | | 2022-01-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3909 | click or scan EU-EC-10011202808 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3910 | click or scan EU-EC-10011202537 | | 2022-01-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Encephalitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Status epilepticus (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3911 | click or scan EU-EC-10011202264 | | 2022-01-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3912 | click or scan EU-EC-10011202218 | | 2022-01-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Right ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Venous thrombosis limb (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3913 | click or scan EU-EC-10011201727 | | 2022-01-10 | Healthcare Professional | EEA | 18-64 Years | Male | Aphasia (4d - Fatal - **Results in Death**), Cerebral infarction (4d - Fatal - **Results in Death**), Headache (4d - Fatal - **Results in Death**), Hemiplegia (4d - Fatal - **Results in Death**), Paraesthesia (4d - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (4d - Fatal - **Results in Death**), Thrombocytopenia (4d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3914 | click or scan EU-EC-10011201468 | | 2022-01-10 | Healthcare Professional | EEA | More than 85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3915 | click or scan EU-EC-10011201419 | | 2022-01-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3916 | click or scan EU-EC-10011201397 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3917 | click or scan EU-EC-10011201342 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3918 | click or scan EU-EC-10011201284 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Agitation (n/a - Unknown - ), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cold sweat (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling hot (n/a - Unknown - ), Haemorrhage intracranial (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown - ), Intracranial pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (2d - Recovered/Resolved - ), Repetitive speech (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Urinary incontinence (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 3919 | click or scan EU-EC-10011201281 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 3920 | click or scan EU-EC-10011201161 | | 2022-01-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3921 | click or scan EU-EC-10011200697 | | 2022-01-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Confusional state (n/a - Unknown - **Results in Death**), Fatigue (3mo - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [8wk - .5mL - Parenteral]) |
| 3922 | click or scan EU-EC-10011200263 | | 2022-01-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3923 | click or scan EU-EC-10011200251 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3924 | click or scan EU-EC-10011200209 | | 2022-01-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3925 | click or scan EU-EC-10011200202 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3926 | click or scan EU-EC-10011200191 | | 2022-01-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Swallow study (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3927 | click or scan EU-EC-10011200179 | | 2022-01-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3928 | click or scan EU-EC-10011200161 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3929 | click or scan EU-EC-10011200156 | | 2022-01-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 3930 | click or scan EU-EC-10011200151 | | 2022-01-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 RNA (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3931 | click or scan EU-EC-10011200148 | | 2022-01-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3932 | click or scan EU-EC-10011198910 | | 2022-01-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3933 | click or scan EU-EC-10011197509 | | 2022-01-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3934 | click or scan EU-EC-10011197407 | | 2022-01-08 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Unknown - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 3935 | click or scan EU-EC-10011197286 | | 2022-01-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bronchial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoptysis (n/a - Fatal - **Results in Death**), Shock haemorrhagic (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), [TREPROSTINIL SODIUM] (S - Product used for unknown indication - Dose not changed - [n/a - n/a - Unknown]) |
| 3936 | click or scan EU-EC-10011196154 | | 2022-01-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3937 | click or scan EU-EC-10011195217 | | 2022-01-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3938 | click or scan EU-EC-10011197202 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood sodium increased (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Computerised tomogram (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Electroencephalogram (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Medical induction of coma (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3939 | click or scan EU-EC-10011197090 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hip fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Open reduction of fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3940 | click or scan EU-EC-10011196981 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sedation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3941 | click or scan EU-EC-10011196943 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (15min - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3942 | click or scan EU-EC-10011196855 | | 2022-01-07 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 3943 | click or scan EU-EC-10011196758 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (9d - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3944 | click or scan EU-EC-10011196696 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Postoperative wound complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3945 | click or scan EU-EC-10011196678 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Activated partial thromboplastin time (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery bypass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vascular graft occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3946 | click or scan EU-EC-10011196613 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Disturbance in attention (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 200ug - Intramuscular]) |
| 3947 | click or scan EU-EC-10011196608 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 3948 | click or scan EU-EC-10011196582 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3949 | click or scan EU-EC-10011196381 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3950 | click or scan EU-EC-10011196379 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3951 | click or scan EU-EC-10011196322 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3952 | click or scan EU-EC-10011196319 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3953 | click or scan EU-EC-10011196218 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Polyuria (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3954 | click or scan EU-EC-10011196180 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3955 | click or scan EU-EC-10011196169 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Erythema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Skin discolouration (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 3956 | click or scan EU-EC-10011196099 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Influenza (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Tachycardia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3957 | click or scan EU-EC-10011196034 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3958 | click or scan EU-EC-10011196031 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bedridden (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neuropathy peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3959 | click or scan EU-EC-10011196006 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3960** | click or scan EU-EC-10011195981 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Intestinal infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Venous thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3961** | click or scan EU-EC-10011195980 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3962** | click or scan EU-EC-10011195826 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3963** | click or scan EU-EC-10011195628 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3964** | click or scan EU-EC-10011195616 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), White blood cell disorder (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3965** | click or scan EU-EC-10011195613 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Headache (0d - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3966** | click or scan EU-EC-10011195541 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Atypical pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3967** | click or scan EU-EC-10011195159 | | 2022-01-07 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3968** | click or scan EU-EC-10011195145 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 50ug - Intramuscular]) |
| **3969** | click or scan EU-EC-10011194942 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3970 | click or scan EU-EC-10011194796 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3971 | click or scan EU-EC-10011194789 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Blood creatinine (n/a - Fatal - **Results in Death**), Blood lactic acid increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Pneumonia bacterial (n/a - Fatal - **Results in Death**), Procalcitonin increased (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Urine analysis normal (n/a - Fatal - **Results in Death**), White blood cell count normal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3972 | click or scan EU-EC-10011194776 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3973 | click or scan EU-EC-10011194585 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cold sweat (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Constipation (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 3974 | click or scan EU-EC-10011194453 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3975 | click or scan EU-EC-10011194367 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3976 | click or scan EU-EC-10011194366 | | 2022-01-07 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 3977 | click or scan EU-EC-10011194328 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac dysfunction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiration abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3978 | click or scan EU-EC-10011194308 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adult failure to thrive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**), Bifascicular block (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Influenza A virus test negative (n/a - Fatal - **Results in Death**), Influenza B virus test (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Nucleic acid test (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Polymerase chain reaction (n/a - Fatal - **Results in Death**), Respiratory syncytial virus test negative (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Uterine leiomyoma (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3979 | click or scan EU-EC-10011194284 |  | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fluid intake reduced (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3980 | click or scan EU-EC-10011194219 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3981 | click or scan EU-EC-10011194175 |  | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3982 | click or scan EU-EC-10011194137 |  | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asymptomatic COVID-19 (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3983 | click or scan EU-EC-10011194127 |  | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Autopsy (n/a - Fatal - **Results in Death**), Cardiac disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3984 | click or scan EU-EC-10011194091 |  | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3985 | click or scan EU-EC-10011194053 |  | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3986 | click or scan EU-EC-10011194052 |  | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 3987 | click or scan EU-EC-10011194044 |  | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3988 | click or scan EU-EC-10011194039 |  | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3989 | click or scan EU-EC-10011194034 |  | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (3mo - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [8wk - .5mL - Parenteral]) |

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|---|---|---|---|---|---|---|---|---|---|
| 3990 | click or scan EU-EC-10011194013 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3991 | click or scan EU-EC-10011194004 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Campylobacter infection (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 3992 | click or scan EU-EC-10011193999 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 3993 | click or scan EU-EC-10011193997 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 3994 | click or scan EU-EC-10011193896 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3995 | click or scan EU-EC-10011193890 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3996 | click or scan EU-EC-10011193837 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3997 | click or scan EU-EC-10011193763 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3998 | click or scan EU-EC-10011193513 | | 2022-01-07 | Healthcare Professional | EEA | 18-64 Years | Female | Pancreatitis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [TAMOXIFEN, TAMOXIFEN CITRATE] (S - Breast cancer - Unknown - [n/a - n/a - Oral]) |
| 3999 | click or scan EU-EC-10011193500 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4000 | click or scan EU-EC-10011193344 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (9d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 4001 | click or scan EU-EC-10011193256 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Respiratory tract infection (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4002 | click or scan EU-EC-10011193176 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiogram pulmonary (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Laboratory test (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 4003 | click or scan EU-EC-10011193143 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4004 | click or scan EU-EC-10011192830 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4005 | click or scan EU-EC-10011192727 | | 2022-01-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4006 | click or scan EU-EC-10011192560 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Capillary leak syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4007 | click or scan EU-EC-10011192445 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Groin pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4008 | click or scan EU-EC-10011192444 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Incomplete course of vaccination (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4009 | click or scan EU-EC-10011192385 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Foetal vascular malperfusion (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4010 | click or scan EU-EC-10011192287 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4011 | click or scan EU-EC-10011192248 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4012 | click or scan EU-EC-10011192247 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4013 | click or scan EU-EC-10011192152 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4014 | click or scan EU-EC-10011192073 | | 2022-01-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4015 | click or scan EU-EC-10011192071 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4016 | click or scan EU-EC-10011192048 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diet refusal (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4017 | click or scan EU-EC-10011192044 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4018 | click or scan EU-EC-10011192041 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4019 | click or scan EU-EC-10011192040 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Leukaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 4020 | click or scan EU-EC-10011192037 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4021 | click or scan EU-EC-10011192034 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4022 | click or scan EU-EC-10011192030 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Erythema multiforme (n/a - Not Recovered/Not Resolved - ), Oedema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4023 | click or scan EU-EC-10011192026 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Muscular weakness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4024 | click or scan EU-EC-10011192023 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4025 | click or scan EU-EC-10011192020 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4026 | click or scan EU-EC-10011192018 | | 2022-01-07 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4027 | click or scan EU-EC-10011192012 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4028 | click or scan EU-EC-10011192011 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4029 | click or scan EU-EC-10011191980 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4030 | click or scan EU-EC-10011191965 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4031 | click or scan EU-EC-10011191964 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4032 | click or scan EU-EC-10011191954 | | 2022-01-07 | Healthcare Professional | EEA | More than 85 Years | Female | Delirium (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4033 | click or scan EU-EC-10011191939 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4034 | click or scan EU-EC-10011191921 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4035 | click or scan EU-EC-10011191916 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4036 | click or scan EU-EC-10011191826 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4037 | click or scan EU-EC-10011191695 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Male | Incisional hernia repair (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4038 | click or scan EU-EC-10011191685 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cellulitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Effusion (n/a - Unknown - ), Erythema (n/a - Unknown - ), Feeling hot (n/a - Unknown - ), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Hypopnoea (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Purpura (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Skin discolouration (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4039 | click or scan EU-EC-10011191684 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myelomonocytic leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Unknown - Other Medically Important Condition), Alanine aminotransferase increased (n/a - Unknown - Other Medically Important Condition), Blood creatine increased (n/a - Unknown - Other Medically Important Condition), Brain natriuretic peptide abnormal (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling hot (n/a - Unknown - ), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4040 | click or scan EU-EC-10011191680 |  | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Disease recurrence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastric cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypernatraemia (n/a - Fatal - **Results in Death**, Life Threatening), Hypokalaemia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4041 | click or scan EU-EC-10011191599 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angiogram cerebral normal (n/a - Fatal - **Results in Death**), Aphasia (n/a - Fatal - **Results in Death**), Arteriogram carotid abnormal (n/a - Fatal - **Results in Death**), Atrioventricular block first degree (n/a - Fatal - **Results in Death**), Blood bicarbonate normal (n/a - Fatal - **Results in Death**), Blood calcium decreased (n/a - Fatal - **Results in Death**), Blood chloride decreased (n/a - Fatal - **Results in Death**), Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood glucose normal (n/a - Fatal - **Results in Death**), Blood potassium normal (n/a - Fatal - **Results in Death**), Blood sodium normal (n/a - Fatal - **Results in Death**), Blood urea normal (n/a - Fatal - **Results in Death**), Cerebral artery stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral atrophy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Computerised tomogram (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**), End stage renal disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoglobin decreased (n/a - Fatal - **Results in Death**), International normalised ratio increased (n/a - Fatal - **Results in Death**), Laboratory test (n/a - Fatal - **Results in Death**), Metabolic function test abnormal (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Platelet count normal (n/a - Fatal - **Results in Death**), Scan with contrast abnormal (n/a - Fatal - **Results in Death**), Troponin normal (n/a - Fatal - **Results in Death**), White blood cell count normal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4042 | click or scan EU-EC-10011191479 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Computerised tomogram normal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4043 | click or scan EU-EC-10011191455 |  | 2022-01-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 4044 | click or scan EU-EC-10011191311 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4045 | click or scan EU-EC-10011191094 |  | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4046 | click or scan EU-EC-10011190943 |  | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4047 | click or scan EU-EC-10011190698 |  | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4048 | click or scan EU-EC-10011190696 |  | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4049 | click or scan EU-EC-10011190551 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4050 | click or scan EU-EC-10011190547 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4051 | click or scan EU-EC-10011190546 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4052 | click or scan EU-EC-10011190454 |  | 2022-01-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4053 | click or scan EU-EC-10011190324 |  | 2022-01-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4054 | click or scan EU-EC-10011190313 |  | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4055 | click or scan EU-EC-10011190303 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4056 | click or scan EU-EC-10011190092 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Female | Fluid retention (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4057 | click or scan EU-EC-10011190086 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 4058 | click or scan EU-EC-10011190011 | | 2022-01-07 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**), Herpes zoster (10d - Fatal - **Results in Death**), Musculoskeletal discomfort (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4059 | click or scan EU-EC-10011190005 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4060 | click or scan EU-EC-10011189999 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4061 | click or scan EU-EC-10011189992 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4062 | click or scan EU-EC-10011189990 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4063 | click or scan EU-EC-10011189976 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiomyopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4064 | click or scan EU-EC-10011189975 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4065 | click or scan EU-EC-10011189970 | | 2022-01-07 | Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4066 | click or scan EU-EC-10011189967 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4067 | click or scan EU-EC-10011189962 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Lung infiltration (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4068 | click or scan EU-EC-10011189958 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4069 | click or scan EU-EC-10011189957 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4070 | click or scan EU-EC-10011189954 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4071 | click or scan EU-EC-10011189946 | | 2022-01-07 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 4072 | click or scan EU-EC-10011189939 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acidosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Hyperkalaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 4073 | click or scan EU-EC-10011189930 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Endocarditis (n/a - Fatal - **Results in Death**), Heart valve operation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4074 | click or scan EU-EC-10011189929 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4075 | click or scan EU-EC-10011189928 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4076 | click or scan EU-EC-10011189853 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4077 | click or scan EU-EC-10011189769 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (6wk - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4078 | click or scan EU-EC-10011189727 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4079 | click or scan EU-EC-10011189589 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anal incontinence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eating disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrolyte imbalance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Imaging procedure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4080 | click or scan EU-EC-10011189488 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4081 | click or scan EU-EC-10011189432 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 4082 | click or scan EU-EC-10011189409 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 4 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4083 | click or scan EU-EC-10011189408 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - Intramuscular]) |
| 4084 | click or scan EU-EC-10011189238 | | 2022-01-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4085 | click or scan EU-EC-10011188662 | | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4086 | click or scan EU-EC-10011188467 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adenovirus test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture urine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dialysis device insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemofiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Occult blood positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Prone position (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory viral panel (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine output decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4087 | click or scan EU-EC-10011188213 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4088 | click or scan EU-EC-10011188211 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Respiratory distress (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 4089 | click or scan EU-EC-10011188137 | | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4090 | click or scan EU-EC-10011188060 | | 2022-01-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4091 | click or scan EU-EC-10011188025 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4092 | click or scan EU-EC-10011187920 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4093 | click or scan EU-EC-10011187918 | | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4094 | click or scan EU-EC-10011187849 | | 2022-01-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Amnesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Anaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cataract (n/a - Not Recovered/Not Resolved - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Unknown - ), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4095 | click or scan EU-EC-10011187842 | | 2022-01-07 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4096 | click or scan EU-EC-10011187839 | | 2022-01-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4097 | click or scan EU-EC-10011187837 | | 2022-01-07 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4098 | click or scan EU-EC-10011187833 | | 2022-01-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4099 | click or scan EU-EC-10011187832 | | 2022-01-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 4100 | click or scan EU-EC-10011187804 | | 2022-01-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4101** | click or scan EU-EC-10011187768 |  | 2022-01-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4102** | click or scan EU-EC-10011187606 |  | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4103** | click or scan EU-EC-10011187591 |  | 2022-01-07 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4104** | click or scan EU-EC-10011187588 |  | 2022-01-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4105** | click or scan EU-EC-10011187509 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4106** | click or scan EU-EC-10011187310 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4107** | click or scan EU-EC-10011187309 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Recovering/Resolving - ), Cough (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinitis (n/a - Recovering/Resolving - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4108** | click or scan EU-EC-10011187237 |  | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4109** | click or scan EU-EC-10011187158 |  | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4110 | click or scan EU-EC-10011187129 |  | 2022-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4111 | click or scan EU-EC-10011185005 |  | 2022-01-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological decompensation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological examination abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Quadriparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skull fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4112 | click or scan EU-EC-10011186046 |  | 2022-01-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Guillain-Barre syndrome (61d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4113 | click or scan EU-EC-10011185407 |  | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4114 | click or scan EU-EC-10011185202 |  | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4115 | click or scan EU-EC-10011185201 |  | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (7d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4116 | click or scan EU-EC-10011185200 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4117 | click or scan EU-EC-10011185198 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4118 | click or scan EU-EC-10011185195 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4119 | click or scan EU-EC-10011185193 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4120 | click or scan EU-EC-10011185191 | | 2022-01-06 | Non Healthcare Professional | EEA | Not Specified | Male | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4121 | click or scan EU-EC-10011185189 | | 2022-01-06 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Stillbirth (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4122 | click or scan EU-EC-10011185188 | | 2022-01-06 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4123 | click or scan EU-EC-10011185184 | | 2022-01-06 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4124 | click or scan EU-EC-10011185183 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4125 | click or scan EU-EC-10011185182 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4126 | click or scan EU-EC-10011185179 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4127 | click or scan EU-EC-10011185177 | | 2022-01-06 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4128 | click or scan EU-EC-10011185173 | | 2022-01-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4129 | click or scan EU-EC-10011185171 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4130 | click or scan EU-EC-10011185165 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4131 | click or scan EU-EC-10011185138 | | 2022-01-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dementia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4132 | click or scan EU-EC-10011185136 | | 2022-01-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4133 | click or scan EU-EC-10011185134 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Influenza (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4134 | click or scan EU-EC-10011185131 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4135 | click or scan EU-EC-10011185129 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4136 | click or scan EU-EC-10011185128 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4137 | click or scan EU-EC-10011185124 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Memory impairment (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4138 | click or scan EU-EC-10011185120 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Muscle twitching (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4139 | click or scan EU-EC-10011185118 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4140 | click or scan EU-EC-10011185117 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 4141 | click or scan EU-EC-10011185113 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Gastrointestinal pain (4d - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4142 | click or scan EU-EC-10011185110 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4143 | click or scan EU-EC-10011185107 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 4144 | click or scan EU-EC-10011185099 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4145 | click or scan EU-EC-10011185073 | | 2022-01-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4146 | click or scan EU-EC-10011185069 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Gastric haemorrhage (n/a - Fatal - **Results in Death**), Intestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4147 | click or scan EU-EC-10011185042 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4148 | click or scan EU-EC-10011185024 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4149 | click or scan EU-EC-10011185000 | | 2022-01-06 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dependence on respirator (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pancreatitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4150 | click or scan EU-EC-10011184953 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4151 | click or scan EU-EC-10011184823 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4152 | click or scan EU-EC-10011184812 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coronary artery thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heart transplant rejection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperventilation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Organising pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition), Thrombotic microangiopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4153 | click or scan EU-EC-10011184580 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Contusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**), Wound (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4154 | click or scan EU-EC-10011184556 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 4155 | click or scan EU-EC-10011184545 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4156 | click or scan EU-EC-10011184531 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 4157 | click or scan EU-EC-10011184520 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Organ failure (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4158 | click or scan EU-EC-10011184517 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4159 | click or scan EU-EC-10011184510 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Paresis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4160 | click or scan EU-EC-10011184509 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4161 | click or scan EU-EC-10011184502 | | 2022-01-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4162 | click or scan EU-EC-10011184463 | | 2022-01-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Petechiae (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 4163 | click or scan EU-EC-10011184460 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary sepsis (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4164 | click or scan EU-EC-10011184455 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4165 | click or scan EU-EC-10011184414 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4166 | click or scan EU-EC-10011184412 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4167 | click or scan EU-EC-10011184409 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4168 | click or scan EU-EC-10011184405 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dyspnoea (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 4169 | click or scan EU-EC-10011184322 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4170 | click or scan EU-EC-10011184299 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Organ failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4171 | click or scan EU-EC-10011184298 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4172 | click or scan EU-EC-10011184256 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4173 | click or scan EU-EC-10011184215 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Influenza (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Organ failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4174 | click or scan EU-EC-10011183642 | | 2022-01-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4175 | click or scan EU-EC-10011183594 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4176 | click or scan EU-EC-10011183588 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4177 | click or scan EU-EC-10011183503 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac flutter (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4178 | click or scan EU-EC-10011183471 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Interstitial lung disease (36d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (36d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), VECTIBIX [PANITUMUMAB] (S - Colorectal cancer metastatic - n/a - [122d - n/a - Intravenous (not otherwise specified)]) |
| 4179 | click or scan EU-EC-10011183457 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [8mo - .3mL - Intramuscular]) |
| 4180 | click or scan EU-EC-10011183427 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4181 | click or scan EU-EC-10011183140 | | 2022-01-06 | Healthcare Professional | EEA | More than 85 Years | Male | Chills (17h - Fatal - **Results in Death**), Respiratory distress (17h - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 4182 | click or scan EU-EC-10011182979 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 4183 | click or scan EU-EC-10011182974 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Endocrine neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mass (n/a - Unknown - ), Neoplasm progression (n/a - Unknown - ), Pain in extremity (3d - Recovered/Resolved - ), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4184 | click or scan EU-EC-10011182920 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4185 | click or scan EU-EC-10011182899 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Female | Erysipelas (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4186 | click or scan EU-EC-10011182897 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Female | Angina pectoris (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4187 | click or scan EU-EC-10011182823 | | 2022-01-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 4188 | click or scan EU-EC-10011182749 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4189 | click or scan EU-EC-10011182734 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Intestinal infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4190 | click or scan EU-EC-10011182687 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4191 | click or scan EU-EC-10011182512 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4192 | click or scan EU-EC-10011181471 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4193 | click or scan EU-EC-10011181251 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4194 | click or scan EU-EC-10011181247 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4195 | click or scan EU-EC-10011181244 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4196 | click or scan EU-EC-10011181162 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4197 | click or scan EU-EC-10011181160 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4198 | click or scan EU-EC-10011180993 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4199 | click or scan EU-EC-10011180951 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Unknown]) |
| 4200 | click or scan EU-EC-10011180951 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Unknown]) |
| 4201 | click or scan EU-EC-10011180793 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4202 | click or scan EU-EC-10011180789 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4203 | click or scan EU-EC-10011180754 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Unknown - ), Aplastic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gingival bleeding (n/a - Unknown - ), Gingival swelling (n/a - Unknown - ), Haemoptysis (n/a - Unknown - ), Headache (n/a - Unknown - ), Oxygen consumption decreased (n/a - Unknown - ), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4204 | click or scan EU-EC-10011180747 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Cardiac disorder (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dehydration (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Gastroenteritis (n/a - Unknown - ), Gastrointestinal disorder (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4205 | click or scan EU-EC-10011180719 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Haemothorax (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4206 | click or scan EU-EC-10011180711 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | C-reactive protein increased (n/a - Unknown - ), Cardiac death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Inflammation (n/a - Fatal - **Results in Death**), White blood cell disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 4207 | click or scan EU-EC-10011180708 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4208 | click or scan EU-EC-10011180694 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | C-reactive protein increased (n/a - Unknown - ), Cachexia (n/a - Unknown - Other Medically Important Condition), Cardiac disorder (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Generalised oedema (n/a - Recovering/Resolving - ), Infection (n/a - Unknown - ), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved With Sequelae - ), Respiratory failure (n/a - Not Recovered/Not Resolved - Life Threatening), Tachypnoea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4209 | click or scan EU-EC-10011180604 | | 2022-01-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4210 | click or scan EU-EC-10011180588 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Muscular weakness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4211 | click or scan EU-EC-10011180405 | | 2022-01-06 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (40min - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4212 | click or scan EU-EC-10011180155 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4213 | click or scan EU-EC-10011180153 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4214 | click or scan EU-EC-10011180152 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Paraparesis (n/a - Fatal - **Results in Death**), Pyrexia (3d - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4215 | click or scan EU-EC-10011180150 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (n/a - Fatal - **Results in Death**), Facial paresis (n/a - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Unknown - ), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - 1 {DF} - Intravenous (not otherwise specified)]) |
| 4216 | click or scan EU-EC-10011179832 | | 2022-01-06 | Healthcare Professional | EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4217 | click or scan EU-EC-10011179672 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4218 | click or scan EU-EC-10011179570 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4219 | click or scan EU-EC-10011179563 | | 2022-01-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hypertension (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4220 | click or scan EU-EC-10011179559 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhinitis (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4221 | click or scan EU-EC-10011179554 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Embolism arterial (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4222 | click or scan EU-EC-10011179553 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4223 | click or scan EU-EC-10011179549 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4224 | click or scan EU-EC-10011179544 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4225 | click or scan EU-EC-10011179471 | | 2022-01-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 4226 | click or scan EU-EC-10011179324 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Flatulence (n/a - Unknown - Other Medically Important Condition), Influenza like illness (121d - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4227 | click or scan EU-EC-10011178755 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4228 | click or scan EU-EC-10011178755 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4229 | click or scan EU-EC-10011178735 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4230 | click or scan EU-EC-10011178575 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4231 | click or scan EU-EC-10011178246 | | 2022-01-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Disseminated intravascular coagulation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatorenal syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperglycaemic hyperosmolar nonketotic syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4232 | click or scan EU-EC-10011178149 | | 2022-01-06 | Healthcare Professional | EEA | 18-64 Years | Male | Diabetic coma (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4233 | click or scan EU-EC-10011177895 | | 2022-01-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hiccups (n/a - Unknown - ), Hypertension (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Throat clearing (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4234 | click or scan EU-EC-10011177709 | | 2022-01-06 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4235 | click or scan EU-EC-10011177414 | | 2022-01-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4236 | click or scan EU-EC-10011177187 | | 2022-01-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4237 | click or scan EU-EC-10011177155 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4238 | click or scan EU-EC-10011177150 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4239 | click or scan EU-EC-10011176729 | | 2022-01-06 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4240 | click or scan EU-EC-10011176708 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4241 | click or scan EU-EC-10011176648 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4242 | click or scan EU-EC-10011176598 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4243 | click or scan EU-EC-10011176596 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Feeling hot (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Intra-abdominal haematoma (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4244 | click or scan EU-EC-10011176462 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4245 | click or scan EU-EC-10011176420 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Night sweats (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4246 | click or scan EU-EC-10011176369 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4247 | click or scan EU-EC-10011176281 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4248 | click or scan EU-EC-10011176146 | | 2022-01-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4249 | click or scan EU-EC-10011175872 | | 2022-01-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Angiopathy (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4250 | click or scan EU-EC-10011175780 | | 2022-01-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4251 | click or scan EU-EC-10011174891 | | 2022-01-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (69d - Fatal - **Results in Death**), Erythema (69d - Fatal - **Results in Death**), Headache (69d - Fatal - **Results in Death**), Pyrexia (69d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4252 | click or scan EU-EC-10011174863 | | 2022-01-06 | Healthcare Professional | EEA | 18-64 Years | Male | Craniocerebral injury (n/a - Fatal - **Results in Death**), Encephalomyelitis (n/a - Fatal - **Results in Death**), Pupillary reflex impaired (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4253 | click or scan EU-EC-10011174816 | | 2022-01-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4254 | click or scan EU-EC-10011174220 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4255 | click or scan EU-EC-10011174080 | | 2022-01-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cognitive disorder (2d - Fatal - **Results in Death**), Condition aggravated (3d - Fatal - **Results in Death**), Respiratory distress (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 4256 | click or scan EU-EC-10011174063 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**), Pneumonia viral (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 4257 | click or scan EU-EC-10011173980 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4258 | click or scan EU-EC-10011173937 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Trismus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 4259 | click or scan EU-EC-10011173635 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolism arterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic artery occlusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic infarction (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 4260 | click or scan EU-EC-10011173563 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4261 | click or scan EU-EC-10011173458 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**), Joint swelling (n/a - Recovered/Resolved - ), Lymphoma (5mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4262 | click or scan EU-EC-10011173116 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4263 | click or scan EU-EC-10011173111 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4264 | click or scan EU-EC-10011173099 | | 2022-01-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4265 | click or scan EU-EC-10011173093 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pelvic venous thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4266 | click or scan EU-EC-10011173088 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4267 | click or scan EU-EC-10011173079 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4268 | click or scan EU-EC-10011173075 | | 2022-01-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4269 | click or scan EU-EC-10011173004 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Hypophagia (n/a - Not Recovered/Not Resolved - ), Mobility decreased (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4270 | click or scan EU-EC-10011172983 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4271 | click or scan EU-EC-10011172982 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Female | Tachycardia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4272 | click or scan EU-EC-10011172977 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4273 | click or scan EU-EC-10011172976 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4274 | click or scan EU-EC-10011172974 | | 2022-01-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4275 | click or scan EU-EC-10011172973 | | 2022-01-05 | Non Healthcare Professional | EEA | Not Specified | Male | Epilepsy (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4276 | click or scan EU-EC-10011172971 | | 2022-01-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Vaginal cancer recurrent (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4277 | click or scan EU-EC-10011172968 | | 2022-01-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Proteinuria (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4278 | click or scan EU-EC-10011172967 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Invasive lobular breast carcinoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4279 | click or scan EU-EC-10011172940 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4280 | click or scan EU-EC-10011172939 | | 2022-01-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4281 | click or scan EU-EC-10011172897 | | 2022-01-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Interchange of vaccine products (n/a - Unknown - ), Lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown - ), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4282 | click or scan EU-EC-10011172789 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Male | Cough (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4283 | click or scan EU-EC-10011172692 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic kidney disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4284 | click or scan EU-EC-10011172671 | | 2022-01-05 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4285 | click or scan EU-EC-10011172524 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyslipidaemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4286 | click or scan EU-EC-10011172523 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4287 | click or scan EU-EC-10011172442 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4288 | click or scan EU-EC-10011172327 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - n/a - [n/a - n/a - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4289 | click or scan EU-EC-10011172327 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - n/a - [n/a - n/a - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4290 | click or scan EU-EC-10011172135 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Ileus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4291 | click or scan EU-EC-10011172073 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Contusion (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4292 | click or scan EU-EC-10011172012 |  | 2022-01-05 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4293 | click or scan EU-EC-10011171977 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4294 | click or scan EU-EC-10011171848 |  | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4295 | click or scan EU-EC-10011171842 |  | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angioedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemodynamic instability (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Obstructive airways disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Oropharyngeal pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Upper airway obstruction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Ventricular fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4296 | click or scan EU-EC-10011171780 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (1d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Pallor (1d - Fatal - **Results in Death**), Seizure (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4297 | click or scan EU-EC-10011171390 |  | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure congestive (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4298 | click or scan EU-EC-10011171304 |  | 2022-01-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4299 | click or scan EU-EC-10011171291 |  | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4300 | click or scan EU-EC-10011171282 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 4301 | click or scan EU-EC-10011171280 | | 2022-01-05 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4302 | click or scan EU-EC-10011171249 | | 2022-01-05 | Healthcare Professional | EEA | More than 85 Years | Male | Herpes zoster (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4303 | click or scan EU-EC-10011171210 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1mL - Intramuscular]) |
| 4304 | click or scan EU-EC-10011170837 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Male | Organising pneumonia (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4305 | click or scan EU-EC-10011170440 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Unknown - ), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4306 | click or scan EU-EC-10011170140 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4307 | click or scan EU-EC-10011170062 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Increased bronchial secretion (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal impairment (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Urine output decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4308 | click or scan EU-EC-10011169815 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Immunisation (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4309 | click or scan EU-EC-10011169771 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4310 | click or scan EU-EC-10011169770 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 4311 | click or scan EU-EC-10011169522 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4312 | click or scan EU-EC-10011169518 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pancreatitis acute (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4313 | click or scan EU-EC-10011169515 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4314 | click or scan EU-EC-10011169446 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4315 | click or scan EU-EC-10011169406 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Heat illness (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4316 | click or scan EU-EC-10011169382 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blister (n/a - Unknown - ), Erythema (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4317 | click or scan EU-EC-10011169364 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4318 | click or scan EU-EC-10011169345 | | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Left ventricular failure (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Not Recovered/Not Resolved - ), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4319 | click or scan EU-EC-10011169343 |  | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Epistaxis (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4320 | click or scan EU-EC-10011169335 |  | 2022-01-05 | Non Healthcare Professional | EEA | Not Specified | Male | Infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4321 | click or scan EU-EC-10011169334 |  | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4322 | click or scan EU-EC-10011169332 |  | 2022-01-05 | Non Healthcare Professional | EEA | 18-64 Years | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4323 | click or scan EU-EC-10011169184 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4324 | click or scan EU-EC-10011169183 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4325 | click or scan EU-EC-10011168875 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4326 | click or scan EU-EC-10011168868 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4327 | click or scan EU-EC-10011168304 |  | 2022-01-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4328 | click or scan EU-EC-10011168129 | | 2022-01-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4329 | click or scan EU-EC-10011167789 | | 2022-01-05 | Healthcare Professional | EEA | 18-64 Years | Female | Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4330 | click or scan EU-EC-10011167724 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4331 | click or scan EU-EC-10011167704 | | 2022-01-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), NOT AVAILABLE [MRNA 1273] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4332 | click or scan EU-EC-10011166798 | | 2022-01-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), SARS-CoV-2 RNA (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4333 | click or scan EU-EC-10011166640 | | 2022-01-05 | Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (90min - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4334 | click or scan EU-EC-10011166554 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Arteriosclerosis (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Mesenteric artery embolism (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4335 | click or scan EU-EC-10011166522 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 4336 | click or scan EU-EC-10011166369 | | 2022-01-05 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4337 | click or scan EU-EC-10011166000 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4338 | click or scan EU-EC-10011165758 | | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4339 | click or scan EU-EC-10011165491 | | 2022-01-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4340 | click or scan EU-EC-10011165316 | | 2022-01-05 | Healthcare Professional | EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4341 | click or scan EU-EC-10011165268 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 4342 | click or scan EU-EC-10011165267 | | 2022-01-05 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4343 | click or scan EU-EC-10011165266 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4344 | click or scan EU-EC-10011165265 | | 2022-01-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4345 | click or scan EU-EC-10011165264 | | 2022-01-05 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 4346 | click or scan EU-EC-10011165240 | | 2022-01-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4347 | click or scan EU-EC-10011165171 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Therapy cessation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4348 | click or scan EU-EC-10011165029 | | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood lactic acid (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemoglobin normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory rate increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - Intramuscular]) |
| 4349 | click or scan EU-EC-10011164619 | | 2022-01-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bilirubin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood electrolytes normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood fibrinogen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactate dehydrogenase (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood magnesium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood osmolarity increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood phosphorus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epigastric discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Failure to thrive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoalbuminaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malnutrition (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic function test normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine analysis normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 4350 | click or scan EU-EC-10011164497 | | 2022-01-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4351 | click or scan EU-EC-10011164325 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tracheostomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tracheostomy tube removal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4352 | click or scan EU-EC-10011164301 |  | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4353 | click or scan EU-EC-10011163950 |  | 2022-01-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Agonal respiration (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Culture urine positive (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Klebsiella test positive (n/a - Fatal - **Results in Death**), Leukopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Urine analysis abnormal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4354 | click or scan EU-EC-10011163929 |  | 2022-01-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4355 | click or scan EU-EC-10011163858 |  | 2022-01-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachyarrhythmia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4356 | click or scan EU-EC-10011163455 |  | 2022-01-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Apallic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (89h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4357 | click or scan EU-EC-10011163136 | | 2022-01-05 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4358 | click or scan EU-EC-10011162401 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Autopsy (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Feeling of body temperature change (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hypertensive cardiomegaly (n/a - Fatal - **Results in Death**), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**), Obesity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4359 | click or scan EU-EC-10011162364 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Chest X-ray (n/a - Fatal - **Results in Death**), Chest tube insertion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4360 | click or scan EU-EC-10011161998 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4361 | click or scan EU-EC-10011161995 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4362 | click or scan EU-EC-10011161993 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4363 | click or scan EU-EC-10011161989 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4364 | click or scan EU-EC-10011161987 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4365 | click or scan EU-EC-10011161983 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4366 | click or scan EU-EC-10011161743 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4367 | click or scan EU-EC-10011161328 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Life Threatening), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4368 | click or scan EU-EC-10011161155 | | 2022-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Influenza (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4369 | click or scan EU-EC-10011161150 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Coronary artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4370 | click or scan EU-EC-10011161148 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4371 | click or scan EU-EC-10011161144 | | 2022-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Influenza (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4372 | click or scan EU-EC-10011161136 | | 2022-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Movement disorder (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4373 | click or scan EU-EC-10011161134 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4374 | click or scan EU-EC-10011161127 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4375 | click or scan EU-EC-10011161124 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4376 | click or scan EU-EC-10011161116 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4377 | click or scan EU-EC-10011161114 | | 2022-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4378 | click or scan EU-EC-10011161092 | | 2022-01-04 | Healthcare Professional | EEA | 18-64 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4379 | click or scan EU-EC-10011161074 | | 2022-01-04 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Brain injury (n/a - Fatal - **Results in Death**), Foetal death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4380 | click or scan EU-EC-10011161034 | | 2022-01-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4381 | click or scan EU-EC-10011160913 | | 2022-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4382 | click or scan EU-EC-10011160905 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4383 | click or scan EU-EC-10011160901 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac dysfunction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Delirium (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hepatic encephalopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypercapnia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Melaena (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Microangiopathy (94d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4384 | click or scan EU-EC-10011160896 | | 2022-01-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4385 | click or scan EU-EC-10011160845 | | 2022-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Ascites (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 4386 | click or scan EU-EC-10011160784 | | 2022-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4387** | click or scan EU-EC-10011160778 | | 2022-01-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Meningoencephalitis herpetic (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4388** | click or scan EU-EC-10011160242 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal loss of weight (n/a - Fatal - **Results in Death**), Autoimmune anaemia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**), Lymphoma (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4389** | click or scan EU-EC-10011160239 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4390** | click or scan EU-EC-10011160232 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4391** | click or scan EU-EC-10011160149 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4392** | click or scan EU-EC-10011160146 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4393** | click or scan EU-EC-10011160146 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4394** | click or scan EU-EC-10011160139 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4395 | click or scan EU-EC-10011160137 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4396 | click or scan EU-EC-10011160132 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4397 | click or scan EU-EC-10011160131 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4398 | click or scan EU-EC-10011160129 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4399 | click or scan EU-EC-10011160125 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4400 | click or scan EU-EC-10011159949 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4401 | click or scan EU-EC-10011159806 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4402 | click or scan EU-EC-10011159580 | | 2022-01-04 | Healthcare Professional | Non EEA | Not Specified | Male | Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Product use issue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4403 | click or scan EU-EC-10011159560 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4404 | click or scan EU-EC-10011159413 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [313d - 1{DF} - Intramuscular]) |
| 4405 | click or scan EU-EC-10011159381 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Male | Peripheral ischaemia (5d - Fatal - **Results in Death**), Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 4406 | click or scan EU-EC-10011159374 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (13d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 4407 | click or scan EU-EC-10011159373 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 4408 | click or scan EU-EC-10011159370 | | 2022-01-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Respiratory distress (4d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4409 | click or scan EU-EC-10011159294 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Parenteral]) |
| 4410 | click or scan EU-EC-10011159279 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Amyloidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 4411 | click or scan EU-EC-10011158992 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - Unknown]) |
| 4412 | click or scan EU-EC-10011158990 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia staphylococcal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sinus operation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4413 | click or scan EU-EC-10011158976 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dysphagia (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Exposure to SARS-CoV-2 (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Lethargy (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4414 | click or scan EU-EC-10011158287 | | 2022-01-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - ), Blister (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Hernia (n/a - Unknown - Other Medically Important Condition), Herpes zoster (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neuralgia (n/a - Unknown - ), Pruritus (n/a - Unknown - ), Rash (n/a - Unknown - ), Weight decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4415 | click or scan EU-EC-10011158265 | | 2022-01-04 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Cytogenetic abnormality (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure before pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 4416 | click or scan EU-EC-10011158123 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4417 | click or scan EU-EC-10011158121 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4418 | click or scan EU-EC-10011158120 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4419 | click or scan EU-EC-10011158119 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4420 | click or scan EU-EC-10011158106 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4421 | click or scan EU-EC-10011158102 | | 2022-01-04 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4422 | click or scan EU-EC-10011158101 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4423 | click or scan EU-EC-10011158098 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4424 | click or scan EU-EC-10011158097 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4425 | click or scan EU-EC-10011157787 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure immeasurable (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypopnoea (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4426 | click or scan EU-EC-10011157561 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4427 | click or scan EU-EC-10011157134 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Left ventricular hypertrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Photosensitivity reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| 4428 | click or scan EU-EC-10011157030 | | 2022-01-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Infection (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Splenic rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4429 | click or scan EU-EC-10011156802 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anticoagulant therapy (n/a - Fatal - **Results in Death**), Autopsy (n/a - Fatal - **Results in Death**), Cardiac disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4430 | click or scan EU-EC-10011156744 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture urine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound kidney (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4431 | click or scan EU-EC-10011156218 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (0d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4432 | click or scan EU-EC-10011156098 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4433 | click or scan EU-EC-10011155794 | | 2022-01-04 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [2mo - .5mL - Intramuscular]) |
| 4434 | click or scan EU-EC-10011155275 | | 2022-01-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4435 | click or scan EU-EC-10011155268 | | 2022-01-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4436 | click or scan EU-EC-10011155222 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4437 | click or scan EU-EC-10011155175 | | 2022-01-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Overgrowth fungal (31d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| 4438 | click or scan EU-EC-10011155147 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4439 | click or scan EU-EC-10011154890 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [84d - .5mL - Intramuscular]) |
| 4440 | click or scan EU-EC-10011154839 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac assistance device user (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral coldness (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4441 | click or scan EU-EC-10011154476 | | 2022-01-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Dyspnoea (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4442 | click or scan EU-EC-10011154440 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4443 | click or scan EU-EC-10011154353 | | 2022-01-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4444 | click or scan EU-EC-10011154335 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4445 | click or scan EU-EC-10011154333 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4446 | click or scan EU-EC-10011154250 | | 2022-01-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4447 | click or scan EU-EC-10011154185 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4448 | click or scan EU-EC-10011153536 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4449 | click or scan EU-EC-10011153497 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4450 | click or scan EU-EC-10011153474 | | 2022-01-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (7d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Therapy cessation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4451 | click or scan EU-EC-10011153316 | | 2022-01-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Pain (n/a - Unknown - ), Pain in extremity (n/a - Fatal - **Results in Death**), Toxicity to various agents (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4452 | click or scan EU-EC-10011153075 | | 2022-01-04 | Non Healthcare Professional | EEA | Not Specified | Male | Asthenia (n/a - Fatal - **Results in Death**), Immunisation (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4453 | click or scan EU-EC-10011153028 | | 2022-01-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4454 | click or scan EU-EC-10011152942 | | 2022-01-04 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4455 | click or scan EU-EC-10011152459 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypersomnia (n/a - Fatal - **Results in Death**), Mental impairment (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4456 | click or scan EU-EC-10011152368 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4457 | click or scan EU-EC-10011152232 | | 2022-01-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4458 | click or scan EU-EC-10011151911 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood gases abnormal (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**), Haemodialysis (n/a - Fatal - **Results in Death**), Life support (n/a - Fatal - **Results in Death**), Mechanical ventilation (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), Renal function test abnormal (n/a - Fatal - **Results in Death**), Respiratory alkalosis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 4459 | click or scan EU-EC-10011151906 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4460 | click or scan EU-EC-10011151363 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4461 | click or scan EU-EC-10011151270 | | 2022-01-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4462 | click or scan EU-EC-10011151097 | | 2022-01-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4463 | click or scan EU-EC-10011150048 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4464 | click or scan EU-EC-10011149910 | | 2022-01-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4465** | click or scan EU-EC-10011149545 | | 2022-01-03 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatotoxicity (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - n/a]), [ARGATROBAN] (S - Anticoagulant therapy - Drug withdrawn - [n/a - n/a - n/a]), [DANAPAROID SODIUM] (S - Thrombocytopenia - Not applicable - [n/a - n/a - n/a]), [FONDAPARINUX] (S - Anticoagulant therapy, Thrombocytopenia - Not applicable - [n/a - 7.5mg - Subcutaneous - More in ICSR]) |
| **4466** | click or scan EU-EC-10011149453 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | Haemolytic anaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4467** | click or scan EU-EC-10011149415 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4468** | click or scan EU-EC-10011149029 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4469** | click or scan EU-EC-10011148830 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4470** | click or scan EU-EC-10011148639 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4471** | click or scan EU-EC-10011148627 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriogram coronary abnormal (n/a - Fatal - **Results in Death**), Brain natriuretic peptide increased (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Electrocardiogram ST segment elevation (n/a - Fatal - **Results in Death**), Fibrin D dimer (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Troponin (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4472** | click or scan EU-EC-10011148476 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colitis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemodynamic test (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhabdomyolysis (168d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinusitis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4473 | click or scan EU-EC-10011148346 |  | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4474 | click or scan EU-EC-10011147629 |  | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4475 | click or scan EU-EC-10011147590 |  | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Immunisation reaction (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4476 | click or scan EU-EC-10011147580 |  | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - 1 {DF} - Intramuscular]), IMBRUVICA 140 MG HARD CAPSULES [IBRUTINIB] (S - Non-Hodgkin's lymphoma - Not applicable - [n/a - 560mg - Oral]) |
| 4477 | click or scan EU-EC-10011147573 |  | 2022-01-03 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (17d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [50d - 1 {DF} - Intramuscular]) |
| 4478 | click or scan EU-EC-10011147553 |  | 2022-01-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4479 | click or scan EU-EC-10011147547 |  | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4480 | click or scan EU-EC-10011147504 |  | 2022-01-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [29d - 1 {DF} - Intramuscular]) |
| 4481 | click or scan EU-EC-10011147479 |  | 2022-01-03 | Healthcare Professional | EEA | Not Specified | Female | Heart disease congenital (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Transplacental]) |
| 4482 | click or scan EU-EC-10011147466 |  | 2022-01-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 4483 | click or scan EU-EC-10011147433 |  | 2022-01-03 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Subcutaneous]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4484** | click or scan EU-EC-10011147068 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4485** | click or scan EU-EC-10011146715 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Autopsy (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Foaming at mouth (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4486** | click or scan EU-EC-10011146498 | | 2022-01-03 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4487** | click or scan EU-EC-10011146495 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4488** | click or scan EU-EC-10011146489 | | 2022-01-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4489** | click or scan EU-EC-10011146446 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4490** | click or scan EU-EC-10011146441 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4491** | click or scan EU-EC-10011146364 | | 2022-01-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Intestinal infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4492** | click or scan EU-EC-10011146287 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4493** | click or scan EU-EC-10011146106 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4494 | click or scan EU-EC-10011145919 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4495 | click or scan EU-EC-10011145917 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4496 | click or scan EU-EC-10011145642 | | 2022-01-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4497 | click or scan EU-EC-10011145641 | | 2022-01-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bladder catheterisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary retention (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4498 | click or scan EU-EC-10011145279 | | 2022-01-03 | Healthcare Professional | Non EEA | Not Specified | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4499 | click or scan EU-EC-10011144851 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4500 | click or scan EU-EC-10011144820 | | 2022-01-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vertigo (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4501 | click or scan EU-EC-10011144780 | | 2022-01-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4502 | click or scan EU-EC-10011144719 | | 2022-01-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Feeling abnormal (n/a - Unknown - ), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4503 | click or scan EU-EC-10011144648 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4504 | click or scan EU-EC-10011144631 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4505 | click or scan EU-EC-10011144627 | | 2022-01-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4506 | click or scan EU-EC-10011144625 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4507 | click or scan EU-EC-10011144560 | | 2022-01-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4508 | click or scan EU-EC-10011144543 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4509 | click or scan EU-EC-10011144027 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4510 | click or scan EU-EC-10011143986 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4511 | click or scan EU-EC-10011143835 | | 2022-01-03 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4512 | click or scan EU-EC-10011143832 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4513 | click or scan EU-EC-10011143828 | | 2022-01-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4514 | click or scan EU-EC-10011143824 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4515 | click or scan EU-EC-10011143821 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4516 | click or scan EU-EC-10011143817 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4517 | click or scan EU-EC-10011143805 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4518 | click or scan EU-EC-10011143803 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4519 | click or scan EU-EC-10011143794 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4520 | click or scan EU-EC-10011143766 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4521 | click or scan EU-EC-10011143224 | | 2022-01-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4522 | click or scan EU-EC-10011143218 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4523 | click or scan EU-EC-10011143029 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4524 | click or scan EU-EC-10011142438 | | 2022-01-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4525 | click or scan EU-EC-10011142371 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4526 | click or scan EU-EC-10011142216 |  | 2022-01-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Anticoagulant therapy (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood urea increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Inflammatory marker increased (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Procalcitonin (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4527 | click or scan EU-EC-10011142138 |  | 2022-01-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4528 | click or scan EU-EC-10011142029 |  | 2022-01-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Extra dose administered (n/a - Recovered/Resolved - ), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4529 | click or scan EU-EC-10011142024 |  | 2022-01-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4530 | click or scan EU-EC-10011141993 |  | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Clumsiness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid retention (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Grip strength decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunoglobulin therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Impaired work ability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4531 | click or scan EU-EC-10011141904 |  | 2022-01-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4532 | click or scan EU-EC-10011141831 |  | 2022-01-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4533 | click or scan EU-EC-10011141712 |  | 2022-01-03 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal cardiac arrest (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Foetal death (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Foetal growth restriction (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4534 | click or scan EU-EC-10011141355 | | 2022-01-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4535 | click or scan EU-EC-10011141177 | | 2022-01-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4536 | click or scan EU-EC-10011140886 | | 2022-01-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Troponin increased (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4537 | click or scan EU-EC-10011140821 | | 2022-01-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 4538 | click or scan EU-EC-10011140429 | | 2022-01-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 4539 | click or scan EU-EC-10011140413 | | 2022-01-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac sarcoidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4540 | click or scan EU-EC-10011140403 | | 2022-01-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4541 | click or scan EU-EC-10011140267 | | 2022-01-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4542 | click or scan EU-EC-10011140167 | | 2022-01-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4543 | click or scan EU-EC-10011139921 | | 2022-01-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4544 | click or scan EU-EC-10011139818 | | 2022-01-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4545 | click or scan EU-EC-10011139329 | | 2022-01-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4546 | click or scan EU-EC-10011138766 | | 2022-01-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4547 | click or scan EU-EC-10011138721 | | 2022-01-01 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4548 | click or scan EU-EC-10011138473 | | 2022-01-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasopharyngitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4549 | click or scan EU-EC-10011138458 | | 2022-01-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4550 | click or scan EU-EC-10011138449 | | 2022-01-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4551 | click or scan EU-EC-10011138284 | | 2022-01-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4552 | click or scan EU-EC-10011137389 | | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4553 | click or scan EU-EC-10011137084 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Alcohol use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood alcohol increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumocephalus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Prothrombin time normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skull fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4554 | click or scan EU-EC-10011137049 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Urinary incontinence (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 4555 | click or scan EU-EC-10011137040 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4556 | click or scan EU-EC-10011136985 | | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac resynchronisation therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Taste disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4557 | click or scan EU-EC-10011136593 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4558 | click or scan EU-EC-10011136266 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4559 | click or scan EU-EC-10011136036 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4560 | click or scan EU-EC-10011135749 | | 2021-12-31 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4561 | click or scan EU-EC-10011135723 | | 2021-12-31 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4562 | click or scan EU-EC-10011135630 | | 2021-12-31 | Healthcare Professional | EEA | Not Specified | Not Specified | Abortion induced (n/a - Fatal - **Results in Death**), Chromosome analysis abnormal (n/a - Unknown - Congenital Anomaly), Ultrasound foetal abnormal (n/a - Unknown - Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2 {DF} - Transplacental]) |
| 4563 | click or scan EU-EC-10011135620 | | 2021-12-31 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 4564 | click or scan EU-EC-10011135510 | | 2021-12-31 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 4565 | click or scan EU-EC-10011135350 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) |
| 4566 | click or scan EU-EC-10011135174 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 4567 | click or scan EU-EC-10011134193 | | 2021-12-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 4568 | click or scan EU-EC-10011133968 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4569 | click or scan EU-EC-10011133966 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4570 | click or scan EU-EC-10011133948 |  | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure abnormal (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - ), Head injury (n/a - Unknown - ), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumothorax (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory rate decreased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4571 | click or scan EU-EC-10011133942 |  | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bacterial infection (n/a - Fatal - **Results in Death**), Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4572 | click or scan EU-EC-10011133940 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [ACENOCOUMAROL] (S - Anticoagulant therapy - Not applicable - [n/a - n/a - Oral]) |
| 4573 | click or scan EU-EC-10011133931 |  | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4574 | click or scan EU-EC-10011133892 |  | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4575 | click or scan EU-EC-10011133832 |  | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4576 | click or scan EU-EC-10011133823 |  | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypersensitivity (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pruritus (n/a - Fatal - **Results in Death**), Swelling (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4577 | click or scan EU-EC-10011132847 |  | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4578 | click or scan EU-EC-10011132371 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4579 | click or scan EU-EC-10011132242 | | 2021-12-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 4580 | click or scan EU-EC-10011132203 | | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Swelling (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4581 | click or scan EU-EC-10011132137 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4582 | click or scan EU-EC-10011132037 | | 2021-12-31 | Non Healthcare Professional | Non EEA | Not Specified | Female | Amnesia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cardiac disorder (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate irregular (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Neoplasm (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4583 | click or scan EU-EC-10011131858 | | 2021-12-31 | Healthcare Professional | EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4584 | click or scan EU-EC-10011131660 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4585 | click or scan EU-EC-10011131642 | | 2021-12-31 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) |
| 4586 | click or scan EU-EC-10011131562 | | 2021-12-31 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (6d - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (6d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4587 | click or scan EU-EC-10011131531 | | 2021-12-31 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4588 | click or scan EU-EC-10011131506 | | 2021-12-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4589 | click or scan EU-EC-10011131502 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4590 | click or scan EU-EC-10011131212 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cyanosis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4591 | click or scan EU-EC-10011131177 | | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Respiratory disorder (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Status epilepticus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4592 | click or scan EU-EC-10011130741 | | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atelectasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superinfection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4593 | click or scan EU-EC-10011130658 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Heart rate abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal obstruction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Surgery (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), X-ray (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4594 | click or scan EU-EC-10011130657 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**), Back pain (1d - Fatal - **Results in Death**), Blood albumin decreased (1d - Fatal - **Results in Death**), Blood alkaline phosphatase increased (1d - Fatal - **Results in Death**), Blood calcium decreased (1d - Fatal - **Results in Death**), Blood creatine phosphokinase (1d - Fatal - **Results in Death**), Blood creatinine increased (1d - Fatal - **Results in Death**), Blood glucose increased (1d - Fatal - **Results in Death**), Blood lactic acid decreased (1d - Fatal - **Results in Death**), Blood urea increased (1d - Fatal - **Results in Death**), Carbon dioxide decreased (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Differential white blood cell count (1d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), Full blood count abnormal (1d - Fatal - **Results in Death**), Haematocrit decreased (1d - Fatal - **Results in Death**), Haemoglobin decreased (1d - Fatal - **Results in Death**), International normalised ratio normal (1d - Fatal - **Results in Death**), Lymphocyte percentage decreased (1d - Fatal - **Results in Death**), Mean cell haemoglobin concentration decreased (1d - Fatal - **Results in Death**), Metabolic function test abnormal (1d - Fatal - **Results in Death**), Monocyte percentage (1d - Fatal - **Results in Death**), Neck pain (1d - Fatal - **Results in Death**), Neutrophil percentage increased (1d - Fatal - **Results in Death**), Prothrombin time (1d - Fatal - **Results in Death**), Red blood cell count decreased (1d - Fatal - **Results in Death**), SARS-CoV-2 test (1d - Fatal - **Results in Death**), Staphylococcus test positive (1d - Fatal - **Results in Death**), Troponin (1d - Fatal - **Results in Death**), White blood cell count increased (1d - Fatal - **Results in Death**), X-ray normal (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4595 | click or scan EU-EC-10011130632 | | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4596 | click or scan EU-EC-10011130429 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4597 | click or scan EU-EC-10011130361 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4598 | click or scan EU-EC-10011130337 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4599 | click or scan EU-EC-10011130314 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Flank pain (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4600 | click or scan EU-EC-10011130280 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fluid retention (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sensory loss (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4601 | click or scan EU-EC-10011130279 |  | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4602 | click or scan EU-EC-10011130242 |  | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoosmolar state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4603 | click or scan EU-EC-10011130115 |  | 2021-12-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4604 | click or scan EU-EC-10011130090 |  | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4605 | click or scan EU-EC-10011130015 | | 2021-12-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**), Aortic dilatation (n/a - Fatal - **Results in Death**), Atypical pneumonia (n/a - Fatal - **Results in Death**), Blood culture (n/a - Fatal - **Results in Death**), Blood lactic acid (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Chest X-ray normal (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Hepatic steatosis (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammatory marker increased (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal cyst (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Splenomegaly (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**), White blood cell count decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4606 | click or scan EU-EC-10011129947 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening), Nasal congestion (n/a - Fatal - **Results in Death**, Life Threatening), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4607 | click or scan EU-EC-10011129676 | | 2021-12-31 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal growth restriction (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 4608 | click or scan EU-EC-10011129657 | | 2021-12-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4609 | click or scan EU-EC-10011129125 | | 2021-12-31 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 4610 | click or scan EU-EC-10011128872 | | 2021-12-31 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (32d - Fatal - **Results in Death**), Diarrhoea (32d - Fatal - **Results in Death**), Pyrexia (32d - Fatal - **Results in Death**), Respiratory failure (32d - Fatal - **Results in Death**), Vaccination failure (32d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 4611 | click or scan EU-EC-10011128734 | | 2021-12-31 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (22d - Fatal - **Results in Death**), Pyrexia (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 4612 | click or scan EU-EC-10011128415 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Injection site pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4613 | click or scan EU-EC-10011128400 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood osmolarity decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4614 | click or scan EU-EC-10011128365 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4615 | click or scan EU-EC-10011128258 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4616 | click or scan EU-EC-10011127987 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Computerised tomogram head normal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Electrocardiogram normal (n/a - Fatal - **Results in Death**), Myocardial necrosis marker normal (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4617 | click or scan EU-EC-10011127933 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | Body temperature increased (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Lacrimation increased (n/a - Recovering/Resolving - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4618 | click or scan EU-EC-10011127928 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lung cancer metastatic (n/a - Fatal - **Results in Death**), Streptococcal infection (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4619 | click or scan EU-EC-10011127793 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspiration pleural cavity (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Chest tube insertion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Therapeutic embolisation (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4620 | click or scan EU-EC-10011127531 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 RNA (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4621 | click or scan EU-EC-10011127490 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4622 | click or scan EU-EC-10011127444 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4623 | click or scan EU-EC-10011127441 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4624 | click or scan EU-EC-10011127354 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4625 | click or scan EU-EC-10011127323 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4626 | click or scan EU-EC-10011127295 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cholinergic syndrome (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4627 | click or scan EU-EC-10011127269 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4628 | click or scan EU-EC-10011127207 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4629 | click or scan EU-EC-10011126385 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4630 | click or scan EU-EC-10011126239 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4631 | click or scan EU-EC-10011126057 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4632 | click or scan EU-EC-10011125946 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4633 | click or scan EU-EC-10011125792 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal wall haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nucleic acid test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4634 | click or scan EU-EC-10011125144 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertensive crisis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - Not applicable - [n/a - n/a - Unknown]), [CLONIDINE HYDROCHLORIDE] (S - Hypertensive crisis - Not applicable - [n/a - .15mg - Intravenous (not otherwise specified)]), [FUROSEMIDE] (S - Hypertensive crisis - Not applicable - [n/a - 20mg - Intravenous (not otherwise specified)]) |
| 4635 | click or scan EU-EC-10011124832 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Life Threatening, Congenital Anomaly, Other Medically Important Condition), Maternal exposure timing unspecified (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 4636 | click or scan EU-EC-10011124828 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cholecystitis infective (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Echocardiogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Effusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4637 | click or scan EU-EC-10011124693 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 RNA (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4638 | click or scan EU-EC-10011124081 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4639 | click or scan EU-EC-10011123527 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain herniation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Foetal vascular malperfusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vasogenic cerebral oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [METAMIZOLE SODIUM] (S - Headache, Pain in extremity - Unknown - [n/a - n/a - n/a]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (S - Urinary tract infection bacterial - Unknown - [n/a - n/a - n/a]) |
| 4640 | click or scan EU-EC-10011123147 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4641 | click or scan EU-EC-10011123015 |  | 2021-12-30 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | ALIMTA [PEMETREXED] (S - Lung adenocarcinoma - Not applicable - [1d - n/a - Intravenous (not otherwise specified)]), KEYTRUDA [PEMBROLIZUMAB] (S - Lung adenocarcinoma - Not applicable - [1d - n/a - Intravenous (not otherwise specified)]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 2 {DF} - Intramuscular]) |
| 4642 | click or scan EU-EC-10011123014 |  | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (25d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4643 | click or scan EU-EC-10011122996 |  | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Influenza like illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 4644 | click or scan EU-EC-10011122990 |  | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Myocarditis (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4645 | click or scan EU-EC-10011122969 |  | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4646 | click or scan EU-EC-10011122763 |  | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Aortic arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Unknown - Other Medically Important Condition), Constipation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Emphysema (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Overflow diarrhoea (n/a - Not Recovered/Not Resolved - ), Sputum discoloured (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4647 | click or scan EU-EC-10011122759 |  | 2021-12-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4648 | click or scan EU-EC-10011122696 |  | 2021-12-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - ), Fall (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4649 | click or scan EU-EC-10011122628 |  | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4650 | click or scan EU-EC-10011121893 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Delirium (n/a - Not Recovered/Not Resolved - Life Threatening), Encephalitis viral (n/a - Unknown - Life Threatening, Other Medically Important Condition), Encephalomyelitis viral (n/a - Unknown - Life Threatening), Epilepsy (0d - Recovered/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Meningoencephalitis viral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4651 | click or scan EU-EC-10011121887 | | 2021-12-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4652 | click or scan EU-EC-10011120919 | | 2021-12-30 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4653 | click or scan EU-EC-10011120797 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4654 | click or scan EU-EC-10011120150 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 4655 | click or scan EU-EC-10011120145 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4656 | click or scan EU-EC-10011120141 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Delusional perception (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Suspected suicide (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4657 | click or scan EU-EC-10011120114 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4658 | click or scan EU-EC-10011119706 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4659 | click or scan EU-EC-10011118941 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac disorder (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4660 | click or scan EU-EC-10011118803 | | 2021-12-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (14d - Unknown - ), Balance disorder (14d - Unknown - ), Decreased appetite (14d - Unknown - ), Diarrhoea (14d - Unknown - ), Hyperhidrosis (14d - Unknown - ), Myocardial infarction (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (14d - Unknown - ) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4661 | click or scan EU-EC-10011118632 | | 2021-12-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Decubitus ulcer (n/a - Fatal - **Results in Death**), Erysipelas (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4662 | click or scan EU-EC-10011118210 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4663 | click or scan EU-EC-10011118194 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4664 | click or scan EU-EC-10011118179 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 pneumonia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4665 | click or scan EU-EC-10011118039 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4666 | click or scan EU-EC-10011117975 | | 2021-12-30 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4667 | click or scan EU-EC-10011117974 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4668 | click or scan EU-EC-10011117972 | | 2021-12-30 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4669 | click or scan EU-EC-10011117971 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4670 | click or scan EU-EC-10011117966 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4671 | click or scan EU-EC-10011117911 | | 2021-12-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4672 | click or scan EU-EC-10011117707 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Unknown - Life Threatening), COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4673 | click or scan EU-EC-10011117706 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4674 | click or scan EU-EC-10011117503 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4675 | click or scan EU-EC-10011117418 | | 2021-12-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dependence on respirator (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4676 | click or scan EU-EC-10011117289 | | 2021-12-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Malaise (n/a - Unknown - ), Neoplasm progression (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4677 | click or scan EU-EC-10011117250 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrioventricular dissociation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood iron decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nodal rhythm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Vitamin B12 decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4678 | click or scan EU-EC-10011116864 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Effusion (n/a - Unknown - ), Malaise (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4679 | click or scan EU-EC-10011116721 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Demyelination (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disturbance in attention (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary incontinence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4680 | click or scan EU-EC-10011116716 | | 2021-12-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4681 | click or scan EU-EC-10011116635 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4682 | click or scan EU-EC-10011116579 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4683 | click or scan EU-EC-10011116576 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4684 | click or scan EU-EC-10011116573 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4685 | click or scan EU-EC-10011116572 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4686 | click or scan EU-EC-10011116567 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4687 | click or scan EU-EC-10011116564 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4688 | click or scan EU-EC-10011116472 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Hypercapnia (n/a - Unknown - ), Hypertension (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Respiratory rate increased (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4689 | click or scan EU-EC-10011116343 | | 2021-12-30 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4690 | click or scan EU-EC-10011116330 | | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 4691 | click or scan EU-EC-10011116285 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4692 | click or scan EU-EC-10011116284 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4693 | click or scan EU-EC-10011116282 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4694 | click or scan EU-EC-10011116280 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4695 | click or scan EU-EC-10011116279 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]), [TRAMADOL HYDROCHLORIDE] (S - Lumbar spinal stenosis - Not applicable - [15d - n/a - Oral]) |
| 4696 | click or scan EU-EC-10011116275 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4697 | click or scan EU-EC-10011116269 | | 2021-12-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4698** | click or scan EU-EC-10011116263 | | 2021-12-30 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4699** | click or scan EU-EC-10011116122 | | 2021-12-30 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **4700** | click or scan EU-EC-10011115872 | | 2021-12-30 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4701** | click or scan EU-EC-10011115815 | | 2021-12-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4702** | click or scan EU-EC-10011115765 | | 2021-12-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4703 | click or scan EU-EC-10011115597 |  | 2021-12-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product use issue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Squamous cell carcinoma of lung (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [1d - n/a - Unknown]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [1d - n/a - Unknown]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Influenza immunisation - Not applicable - [1d - n/a - Unknown]) |
| 4704 | click or scan EU-EC-10011115163 |  | 2021-12-30 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebrovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4705 | click or scan EU-EC-10011114549 |  | 2021-12-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Fatal - **Results in Death**), Myelopathy (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 4706 | click or scan EU-EC-10011114284 |  | 2021-12-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (74d - Fatal - **Results in Death**), Pneumonia (74d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 4707 | click or scan EU-EC-10011113585 |  | 2021-12-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Incontinence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4708 | click or scan EU-EC-10011113455 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | Myelodysplastic syndrome (50d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4709 | click or scan EU-EC-10011113179 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4710 | click or scan EU-EC-10011112861 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4711 | click or scan EU-EC-10011112588 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Muscular weakness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4712 | click or scan EU-EC-10011112277 |  | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Female | Brain neoplasm (2mo - Fatal - **Results in Death**), Hormone level abnormal (2mo - Fatal - **Results in Death**), Paraesthesia (2mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4713 | click or scan EU-EC-10011112276 |  | 2021-12-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4714 | click or scan EU-EC-10011112267 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Pulmonary fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4715 | click or scan EU-EC-10011112213 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4716 | click or scan EU-EC-10011111880 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Influenza (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4717 | click or scan EU-EC-10011111844 |  | 2021-12-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4718 | click or scan EU-EC-10011111433 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4719 | click or scan EU-EC-10011111432 |  | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Muscle twitching (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4720 | click or scan EU-EC-10011111087 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4721 | click or scan EU-EC-10011111085 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4722 | click or scan EU-EC-10011111081 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4723 | click or scan EU-EC-10011111075 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4724 | click or scan EU-EC-10011111074 |  | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4725 | click or scan EU-EC-10011111065 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4726 | click or scan EU-EC-10011110735 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 4727 | click or scan EU-EC-10011110114 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | Immunisation reaction (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4728 | click or scan EU-EC-10011110055 |  | 2021-12-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Amnesia (n/a - Not Recovered/Not Resolved - ), Eye haemorrhage (n/a - Recovered/Resolved - ), Gastrointestinal disorder (n/a - Not Recovered/Not Resolved - ), Ischaemic stroke (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Meningoencephalitis herpetic (n/a - Fatal - **Results in Death**), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4729 | click or scan EU-EC-10011110035 |  | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4730 | click or scan EU-EC-10011110007 | | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemosiderosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Waterhouse-Friderichsen syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4731 | click or scan EU-EC-10011109975 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 4732 | click or scan EU-EC-10011109959 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4733 | click or scan EU-EC-10011109667 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Muscle spasms (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 4734 | click or scan EU-EC-10011109498 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemoptysis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4735 | click or scan EU-EC-10011109136 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4736 | click or scan EU-EC-10011109134 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4737 | click or scan EU-EC-10011109133 | | 2021-12-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4738 | click or scan EU-EC-10011109129 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4739 | click or scan EU-EC-10011109122 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4740 | click or scan EU-EC-10011109118 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4741 | click or scan EU-EC-10011109116 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4742 | click or scan EU-EC-10011109019 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4743 | click or scan EU-EC-10011108814 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4744 | click or scan EU-EC-10011108572 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4745 | click or scan EU-EC-10011108505 | | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Female | Chills (4d - Fatal - **Results in Death**), Diarrhoea (4d - Fatal - **Results in Death**), Viral infection (4d - Fatal - **Results in Death**), Vomiting (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4746 | click or scan EU-EC-10011108495 | | 2021-12-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4747 | click or scan EU-EC-10011108401 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Life Threatening), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening), Rash (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4748 | click or scan EU-EC-10011108118 | | 2021-12-29 | Non Healthcare Professional | Non EEA | Not Specified | Female | Foetal cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal vascular malperfusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 4749 | click or scan EU-EC-10011108111 | | 2021-12-29 | Healthcare Professional | EEA | Not Specified | Male | Rheumatoid arthritis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4750 | click or scan EU-EC-10011108003 | | 2021-12-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4751 | click or scan EU-EC-10011107692 | | 2021-12-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4752 | click or scan EU-EC-10011107640 | | 2021-12-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gaze palsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4753 | click or scan EU-EC-10011107610 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**), Arrhythmogenic right ventricular dysplasia (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4754 | click or scan EU-EC-10011107583 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Craniectomy (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4755 | click or scan EU-EC-10011107500 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4756 | click or scan EU-EC-10011107401 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4757 | click or scan EU-EC-10011107264 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4758 | click or scan EU-EC-10011107193 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diabetes mellitus (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4759 | click or scan EU-EC-10011107106 | | 2021-12-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Not Recovered/Not Resolved - ), Pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4760 | click or scan EU-EC-10011107037 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 4761 | click or scan EU-EC-10011107030 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4762 | click or scan EU-EC-10011107028 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4763 | click or scan EU-EC-10011107022 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4764 | click or scan EU-EC-10011107021 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Functional gastrointestinal disorder (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Muscle fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4765 | click or scan EU-EC-10011107019 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 4766 | click or scan EU-EC-10011106992 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling), Somnolence (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 4767 | click or scan EU-EC-10011106765 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea at rest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4768 | click or scan EU-EC-10011106763 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening), Haematoma (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4769 | click or scan EU-EC-10011106761 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4770 | click or scan EU-EC-10011106757 | | 2021-12-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Oedema peripheral (n/a - Fatal - **Results in Death**, Life Threatening), Productive cough (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4771 | click or scan EU-EC-10011106539 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4772 | click or scan EU-EC-10011106535 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4773 | click or scan EU-EC-10011106533 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4774 | click or scan EU-EC-10011106532 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4775 | click or scan EU-EC-10011106531 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4776 | click or scan EU-EC-10011106077 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4777 | click or scan EU-EC-10011106060 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4778 | click or scan EU-EC-10011105999 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4779 | click or scan EU-EC-10011105884 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 4780 | click or scan EU-EC-10011105844 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4781** | click or scan EU-EC-10011105756 |  | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4782** | click or scan EU-EC-10011105752 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4783** | click or scan EU-EC-10011105751 |  | 2021-12-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Generalised oedema (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Neuroendocrine tumour of the lung metastatic (30d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - ) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4784** | click or scan EU-EC-10011105676 |  | 2021-12-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral ischaemia (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4785** | click or scan EU-EC-10011105650 |  | 2021-12-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4786** | click or scan EU-EC-10011105633 |  | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Head injury (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **4787** | click or scan EU-EC-10011105526 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4788** | click or scan EU-EC-10011105515 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4789** | click or scan EU-EC-10011105513 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4790** | click or scan EU-EC-10011105510 |  | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4791 | click or scan EU-EC-10011105509 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4792 | click or scan EU-EC-10011105493 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4793 | click or scan EU-EC-10011105488 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4794 | click or scan EU-EC-10011105105 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 4795 | click or scan EU-EC-10011105037 |  | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4796 | click or scan EU-EC-10011105022 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4797 | click or scan EU-EC-10011105018 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4798 | click or scan EU-EC-10011105010 |  | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4799 | click or scan EU-EC-10011105008 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4800 | click or scan EU-EC-10011105006 |  | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4801 | click or scan EU-EC-10011105003 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4802 | click or scan EU-EC-10011104954 | | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (7d - Fatal - **Results in Death**), Hypophagia (7d - Fatal - **Results in Death**), Somnolence (7d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 4803 | click or scan EU-EC-10011104899 | | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4804 | click or scan EU-EC-10011104834 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4805 | click or scan EU-EC-10011104832 | | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4806 | click or scan EU-EC-10011104828 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4807 | click or scan EU-EC-10011104827 | | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4808 | click or scan EU-EC-10011104822 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4809 | click or scan EU-EC-10011104818 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4810 | click or scan EU-EC-10011104817 | | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4811 | click or scan EU-EC-10011104607 | | 2021-12-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4812 | click or scan EU-EC-10011104530 | | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4813 | click or scan EU-EC-10011104521 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4814 | click or scan EU-EC-10011104509 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4815 | click or scan EU-EC-10011104503 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4816 | click or scan EU-EC-10011104498 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4817 | click or scan EU-EC-10011104494 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4818 | click or scan EU-EC-10011104285 | | 2021-12-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4819 | click or scan EU-EC-10011104233 | | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4820 | click or scan EU-EC-10011104227 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4821 | click or scan EU-EC-10011104224 | | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4822 | click or scan EU-EC-10011104218 | | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4823 | click or scan EU-EC-10011104209 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4824 | click or scan EU-EC-10011104160 | | 2021-12-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspepsia (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4825 | click or scan EU-EC-10011104142 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4826 | click or scan EU-EC-10011104053 | | 2021-12-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4827 | click or scan EU-EC-10011103804 | | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4828 | click or scan EU-EC-10011103751 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4829 | click or scan EU-EC-10011103736 | | 2021-12-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4830 | click or scan EU-EC-10011103733 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4831** | click or scan EU-EC-10011103732 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4832** | click or scan EU-EC-10011103729 | | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4833** | click or scan EU-EC-10011103720 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4834** | click or scan EU-EC-10011103541 | | 2021-12-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (1d - Recovered/Resolved - ), Limb discomfort (n/a - Unknown - ), Musculoskeletal chest pain (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venous thrombosis limb (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4835** | click or scan EU-EC-10011103539 | | 2021-12-29 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4836** | click or scan EU-EC-10011103538 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4837** | click or scan EU-EC-10011103536 | | 2021-12-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4838** | click or scan EU-EC-10011103085 | | 2021-12-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Chest pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4839 | click or scan EU-EC-10011102955 |  | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Angiogram cerebral abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gaze palsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological examination abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Perfusion brain scan abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Prone position (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4840 | click or scan EU-EC-10011102876 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4841 | click or scan EU-EC-10011102415 |  | 2021-12-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) |
| 4842 | click or scan EU-EC-10011102402 |  | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Liver function test abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 4843 | click or scan EU-EC-10011102345 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4844 | click or scan EU-EC-10011102321 |  | 2021-12-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4845 | click or scan EU-EC-10011102246 |  | 2021-12-29 | Healthcare Professional | EEA | Not Specified | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4846 | click or scan EU-EC-10011102176 |  | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4847 | click or scan EU-EC-10011102154 |  | 2021-12-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4848 | click or scan EU-EC-10011101950 |  | 2021-12-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 4849 | click or scan EU-EC-10011101840 |  | 2021-12-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| 4850 | click or scan EU-EC-10011101545 |  | 2021-12-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Gingival abscess (n/a - Fatal - **Results in Death**), Mouth swelling (n/a - Fatal - **Results in Death**), Noninfective gingivitis (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**), White blood cell disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 4851 | click or scan EU-EC-10011101096 |  | 2021-12-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Product used for unknown indication - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4852 | click or scan EU-EC-10011100532 |  | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4853 | click or scan EU-EC-10011100464 |  | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4854** | click or scan EU-EC-10011100343 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4855** | click or scan EU-EC-10011099718 | | 2021-12-28 | Healthcare Professional | EEA | More than 85 Years | Male | Balance disorder (n/a - Not Recovered/Not Resolved - ), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Hypophagia (n/a - Fatal - **Results in Death**), Malaise (2d - Recovering/Resolving - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (2d - Recovering/Resolving - ), Somnolence (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [MICONAZOLE NITRATE] (S - n/a - Dose not changed - [n/a - n/a - n/a]), [NOT AVAILABLE] (S - n/a - Dose not changed - [n/a - n/a - n/a]) |
| **4856** | click or scan EU-EC-10011099635 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| **4857** | click or scan EU-EC-10011099631 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac disorder (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Pancreatic disorder (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4858** | click or scan EU-EC-10011099587 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Artery dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Autoimmune haemolytic anaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Autoimmune haemolytic anaemia (n/a - Unknown - Other Medically Important Condition), Blister (n/a - Unknown - Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Erythema (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Liver disorder (n/a - Unknown - Other Medically Important Condition), Metabolic acidosis (n/a - Unknown - Other Medically Important Condition), Mouth haemorrhage (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Musculoskeletal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Skin disorder (n/a - Unknown - Other Medically Important Condition), Splenic infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Stevens-Johnson syndrome (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - Other Medically Important Condition), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4859** | click or scan EU-EC-10011099504 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Hypothyroidism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4860** | click or scan EU-EC-10011099373 | | 2021-12-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Asthenia (1d - Fatal - **Results in Death**), Chills (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4861** | click or scan EU-EC-10011099199 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4862 | click or scan EU-EC-10011099118 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Insomnia (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 4863 | click or scan EU-EC-10011099051 | | 2021-12-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Malignant neoplasm progression (n/a - Fatal - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), IMMUNOTHERAPIE (IMMUUNTHERAPIE) [NOT AVAILABLE] (S - Neoplasm malignant - Drug withdrawn - [n/a - n/a - n/a]) |
| 4864 | click or scan EU-EC-10011098980 | | 2021-12-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chronic sinusitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Epilepsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Posture abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 4865 | click or scan EU-EC-10011098688 | | 2021-12-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4866 | click or scan EU-EC-10011098430 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4867 | click or scan EU-EC-10011098134 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4868 | click or scan EU-EC-10011097224 | | 2021-12-28 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (48h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [257d - 1 {DF} - Intramuscular]) |
| 4869 | click or scan EU-EC-10011097189 | | 2021-12-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 4870 | click or scan EU-EC-10011097186 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4871 | click or scan EU-EC-10011097162 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | Autoimmune hepatitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4872 | click or scan EU-EC-10011097064 | | 2021-12-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4873 | click or scan EU-EC-10011096970 | | 2021-12-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - ), Colon cancer (n/a - Fatal - **Results in Death**), Metastases to spleen (n/a - Fatal - **Results in Death**), Recurrent cancer (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4874 | click or scan EU-EC-10011096958 | | 2021-12-28 | Healthcare Professional | EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4875 | click or scan EU-EC-10011096767 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4876 | click or scan EU-EC-10011096760 | | 2021-12-28 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4877 | click or scan EU-EC-10011096758 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4878 | click or scan EU-EC-10011096757 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4879 | click or scan EU-EC-10011096748 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4880 | click or scan EU-EC-10011096742 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4881 | click or scan EU-EC-10011096646 | | 2021-12-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4882 | click or scan EU-EC-10011095961 | | 2021-12-28 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4883 | click or scan EU-EC-10011095732 | | 2021-12-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Leukaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Rash macular (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Spinal pain (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4884 | click or scan EU-EC-10011095547 | | 2021-12-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4885 | click or scan EU-EC-10011095545 | | 2021-12-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4886 | click or scan EU-EC-10011095191 | | 2021-12-28 | Healthcare Professional | Non EEA | Not Specified | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4887 | click or scan EU-EC-10011095190 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4888 | click or scan EU-EC-10011095171 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Congestive cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4889 | click or scan EU-EC-10011095166 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4890 | click or scan EU-EC-10011095164 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4891 | click or scan EU-EC-10011095163 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4892 | click or scan EU-EC-10011095157 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4893 | click or scan EU-EC-10011095154 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4894 | click or scan EU-EC-10011095015 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fall (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4895 | click or scan EU-EC-10011094943 | | 2021-12-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4896 | click or scan EU-EC-10011094942 | | 2021-12-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4897 | click or scan EU-EC-10011094739 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4898 | click or scan EU-EC-10011094561 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hepatic failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4899 | click or scan EU-EC-10011094180 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4900 | click or scan EU-EC-10011093863 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 4901 | click or scan EU-EC-10011093678 | | 2021-12-28 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - n/a - [n/a - .5mL - Intramuscular]) |
| 4902 | click or scan EU-EC-10011093590 | | 2021-12-28 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4903 | click or scan EU-EC-10011093366 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | Delirium (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Herpes zoster meningoencephalitis (n/a - Fatal - **Results in Death**), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4904 | click or scan EU-EC-10011093224 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4905 | click or scan EU-EC-10011093173 | | 2021-12-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4906 | click or scan EU-EC-10011093074 | | 2021-12-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ascites (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Hypoalbuminaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), International normalised ratio increased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Jaundice (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 4907 | click or scan EU-EC-10011093004 | | 2021-12-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 4908 | click or scan EU-EC-10011092991 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (5min - Recovering/Resolving - **Results in Death**), Loss of consciousness (5min - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 4909 | click or scan EU-EC-10011092775 | | 2021-12-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (29d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4910 | click or scan EU-EC-10011092722 | | 2021-12-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiogenic shock (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 4911 | click or scan EU-EC-10011092328 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4912 | click or scan EU-EC-10011092205 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4913 | click or scan EU-EC-10011092113 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4914 | click or scan EU-EC-10011092096 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 4915 | click or scan EU-EC-10011092093 | | 2021-12-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4916 | click or scan EU-EC-10011092087 | | 2021-12-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Paralysis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 4917 | click or scan EU-EC-10011092073 | | 2021-12-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Renal cyst (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 4918 | click or scan EU-EC-10011091941 | | 2021-12-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4919 | click or scan EU-EC-10011091469 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4920 | click or scan EU-EC-10011091462 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4921** | click or scan EU-EC-10011091291 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4922** | click or scan EU-EC-10011091276 | | 2021-12-28 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4923** | click or scan EU-EC-10011091241 | | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| **4924** | click or scan EU-EC-10011091129 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4925** | click or scan EU-EC-10011091124 | | 2021-12-28 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4926** | click or scan EU-EC-10011091119 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4927** | click or scan EU-EC-10011091118 | | 2021-12-28 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4928** | click or scan EU-EC-10011091109 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4929** | click or scan EU-EC-10011091107 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4930 | click or scan EU-EC-10011091101 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4931 | click or scan EU-EC-10011091099 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4932 | click or scan EU-EC-10011091087 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4933 | click or scan EU-EC-10011090951 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4934 | click or scan EU-EC-10011090917 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4935 | click or scan EU-EC-10011090717 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4936 | click or scan EU-EC-10011090716 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4937 | click or scan EU-EC-10011090715 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4938 | click or scan EU-EC-10011090714 | | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4939 | click or scan EU-EC-10011090713 | | 2021-12-28 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4940 | click or scan EU-EC-10011090712 |  | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4941 | click or scan EU-EC-10011090711 |  | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4942 | click or scan EU-EC-10011090710 |  | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4943 | click or scan EU-EC-10011090583 |  | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4944 | click or scan EU-EC-10011090582 |  | 2021-12-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4945 | click or scan EU-EC-10011090486 |  | 2021-12-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4946 | click or scan EU-EC-10011090388 |  | 2021-12-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Back pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cholecystitis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Spleen ischaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Tissue infiltration (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 4947 | click or scan EU-EC-10011089923 |  | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**), Neoplasm progression (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4948 | click or scan EU-EC-10011089909 |  | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 4949 | click or scan EU-EC-10011089746 |  | 2021-12-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4950 | click or scan EU-EC-10011088429 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4951 | click or scan EU-EC-10011088320 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4952 | click or scan EU-EC-10011088310 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4953 | click or scan EU-EC-10011088212 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**), Plasma cell myeloma (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4954 | click or scan EU-EC-10011088206 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4955 | click or scan EU-EC-10011088203 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4956 | click or scan EU-EC-10011088193 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4957 | click or scan EU-EC-10011088181 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4958 | click or scan EU-EC-10011088116 | | 2021-12-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Computerised tomogram head normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injection site pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 4959 | click or scan EU-EC-10011088078 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hepatitis C (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 4960 | click or scan EU-EC-10011087647 | | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (4mo - Fatal - **Results in Death**), Brain neoplasm (4mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 4961 | click or scan EU-EC-10011087457 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4962 | click or scan EU-EC-10011087404 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Abscess (n/a - Unknown - Caused/Prolonged Hospitalisation), Bacterial infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pancreatic failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 4963 | click or scan EU-EC-10011087366 | | 2021-12-27 | Healthcare Professional | Non EEA | Not Specified | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4964 | click or scan EU-EC-10011087345 | | 2021-12-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperpyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 4965 | click or scan EU-EC-10011087174 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4966 | click or scan EU-EC-10011086989 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Asthma (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4967 | click or scan EU-EC-10011086946 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 4968 | click or scan EU-EC-10011086863 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Electrolyte imbalance (n/a - Fatal - **Results in Death**), Gastroenteritis (n/a - Fatal - **Results in Death**), Hypoglycaemia (n/a - Fatal - **Results in Death**), Metabolic encephalopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4969 | click or scan EU-EC-10011086835 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4970 | click or scan EU-EC-10011086828 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4971 | click or scan EU-EC-10011086804 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acidosis (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ), Shock (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 4972 | click or scan EU-EC-10011086688 | | 2021-12-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Diabetes mellitus (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4973 | click or scan EU-EC-10011086644 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 4974 | click or scan EU-EC-10011086361 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4975 | click or scan EU-EC-10011086360 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Arteriosclerosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4976 | click or scan EU-EC-10011086219 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4977 | click or scan EU-EC-10011086092 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4978 | click or scan EU-EC-10011086090 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4979 | click or scan EU-EC-10011086084 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4980 | click or scan EU-EC-10011085631 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (43d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4981 | click or scan EU-EC-10011085150 |  | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 4982 | click or scan EU-EC-10011085122 |  | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (11d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [69d - 1{DF} - Intramuscular]) |
| 4983 | click or scan EU-EC-10011085089 |  | 2021-12-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 4984 | click or scan EU-EC-10011084923 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2{DF} - Intramuscular]) |
| 4985 | click or scan EU-EC-10011084919 |  | 2021-12-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 1{DF} - Intramuscular]) |
| 4986 | click or scan EU-EC-10011084918 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [70d - 2{DF} - Intramuscular]) |
| 4987 | click or scan EU-EC-10011084884 |  | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 4988 | click or scan EU-EC-10011084652 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4989 | click or scan EU-EC-10011084650 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4990 | click or scan EU-EC-10011084648 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4991 | click or scan EU-EC-10011084643 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 4992 | click or scan EU-EC-10011084627 | | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4993 | click or scan EU-EC-10011084621 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 4994 | click or scan EU-EC-10011084577 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4995 | click or scan EU-EC-10011084406 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 4996 | click or scan EU-EC-10011084180 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 4997 | click or scan EU-EC-10011084179 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 4998 | click or scan EU-EC-10011084145 | | 2021-12-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arthralgia (n/a - Recovering/Resolving - ), Cerebrovascular accident (n/a - Unknown - ), Chills (56d - Recovered/Resolved - ), Delirium (n/a - Unknown - ), Fall (n/a - Unknown - ), Fatigue (56d - Recovering/Resolving - ), Headache (56d - Recovered/Resolved - ), Malaise (56d - Recovered/Resolved - ), Mobility decreased (n/a - Recovering/Resolving - ), Myalgia (56d - Recovered/Resolved - ), Nausea (56d - Recovered/Resolved - ), Pneumonia (14d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 4999 | click or scan EU-EC-10011084096 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5000 | click or scan EU-EC-10011083995 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5001 | click or scan EU-EC-10011083983 | | 2021-12-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - ), Immunisation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5002 | click or scan EU-EC-10011083928 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5003 | click or scan EU-EC-10011083655 | | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 5004 | click or scan EU-EC-10011083389 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5005 | click or scan EU-EC-10011083387 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5006 | click or scan EU-EC-10011083386 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5007 | click or scan EU-EC-10011083382 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event (n/a - Unknown - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Unknown - **Results in Death**), Neoplasm (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5008 | click or scan EU-EC-10011083273 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), Blood urea nitrogen/creatinine ratio increased (n/a - Unknown - ), Gastrointestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphocyte percentage decreased (n/a - Unknown - ), Neutrophil percentage increased (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Petechiae (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Post procedural haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Purpura (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count increased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5009 | click or scan EU-EC-10011083185 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5010 | click or scan EU-EC-10011083008 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5011 | click or scan EU-EC-10011083007 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5012 | click or scan EU-EC-10011083005 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5013 | click or scan EU-EC-10011083004 |  | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5014 | click or scan EU-EC-10011083003 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5015 | click or scan EU-EC-10011083002 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5016 | click or scan EU-EC-10011083001 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5017 | click or scan EU-EC-10011083000 |  | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5018 | click or scan EU-EC-10011082999 |  | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5019 | click or scan EU-EC-10011082998 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5020 | click or scan EU-EC-10011082997 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5021 | click or scan EU-EC-10011082996 |  | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5022 | click or scan EU-EC-10011082995 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5023 | click or scan EU-EC-10011082983 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bilirubin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bronchoscopy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac telemetry abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Catheter placement (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Enteral nutrition (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatobiliary scan normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Klebsiella test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lipase normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripancreatic fluid collection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonitis aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Serratia test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transaminases increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5024 | click or scan EU-EC-10011082964 | | 2021-12-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (28d - Unknown - Caused/Prolonged Hospitalisation), Acute kidney injury (3d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (10d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5025 | click or scan EU-EC-10011082942 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5026 | click or scan EU-EC-10011082565 | | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5027 | click or scan EU-EC-10011082376 | | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5028 | click or scan EU-EC-10011082227 | | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 5029 | click or scan EU-EC-10011082219 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | Pain in extremity (6d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5030 | click or scan EU-EC-10011082177 | | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5031 | click or scan EU-EC-10011082077 | | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Female | Brain death (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 5032 | click or scan EU-EC-10011081665 | | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cognitive disorder (n/a - Not Recovered/Not Resolved - ), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysphagia (n/a - Not Recovered/Not Resolved - ), Mutism (n/a - Not Recovered/Not Resolved - ), Vascular parkinsonism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5033 | click or scan EU-EC-10011081600 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5034 | click or scan EU-EC-10011081490 | | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5035 | click or scan EU-EC-10011081486 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5036 | click or scan EU-EC-10011081478 | | 2021-12-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **5037** | click or scan EU-EC-10011081281 | | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **5038** | click or scan EU-EC-10011081213 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **5039** | click or scan EU-EC-10011081134 | | 2021-12-27 | Healthcare Professional | EEA | Not Specified | Female | Bedridden (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pulmonary hypertension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **5040** | click or scan EU-EC-10011080854 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Colectomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colostomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exploratory operation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Volvulus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5041 | click or scan EU-EC-10011080680 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebellar infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral arteriosclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral atrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral small vessel ischaemic disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic sinusitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalomalacia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Enteral nutrition (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mucosal hypertrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Spinal osteoarthritis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 5042 | click or scan EU-EC-10011080626 | | 2021-12-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Dementia (n/a - Fatal - **Results in Death**), Dyspnoea at rest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5043 | click or scan EU-EC-10011080614 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | Breast pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5044 | click or scan EU-EC-10011080088 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5045 | click or scan EU-EC-10011080082 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5046 | click or scan EU-EC-10011080067 | | 2021-12-27 | Healthcare Professional | EEA | 18-64 Years | Male | Acidosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Acute kidney injury (1d - Fatal - **Results in Death**), Acute respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral ischaemia (1d - Fatal - **Results in Death**), Sepsis (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5047 | click or scan EU-EC-10011080025 | | 2021-12-27 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5048 | click or scan EU-EC-10011079871 | | 2021-12-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 5049 | click or scan EU-EC-10011079868 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5050 | click or scan EU-EC-10011079858 | | 2021-12-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5051 | click or scan EU-EC-10011079736 | | 2021-12-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 5052 | click or scan EU-EC-10011079735 | | 2021-12-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 5053 | click or scan EU-EC-10011079726 | | 2021-12-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5054 | click or scan EU-EC-10011079619 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Shock haemorrhagic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5055 | click or scan EU-EC-10011079577 | | 2021-12-27 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Frequent bowel movements (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5056 | click or scan EU-EC-10011079328 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5057 | click or scan EU-EC-10011079280 | | 2021-12-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Polyuria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5058 | click or scan EU-EC-10011079189 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5059 | click or scan EU-EC-10011078874 | | 2021-12-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (0d - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]), FLUAD TETRA [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Influenza immunisation - Not applicable - [n/a - .5mL - Unknown]), FLUAD TETRA [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Influenza immunisation - Not applicable - [n/a - 12mL - n/a]), [COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]), [INFLUENZA VIRUS] (S - Immunisation, Influenza immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5060 | click or scan EU-EC-10011078790 | | 2021-12-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Accident (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5061 | click or scan EU-EC-10011078645 | | 2021-12-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5062 | click or scan EU-EC-10011078393 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5063 | click or scan EU-EC-10011078365 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5064 | click or scan EU-EC-10011078282 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5065 | click or scan EU-EC-10011078240 | | 2021-12-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product use issue (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [INFLUENZA VIRUS] (S - Influenza immunisation - Not applicable - [1d - n/a - n/a]) |
| 5066 | click or scan EU-EC-10011078207 | | 2021-12-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Joint stiffness (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 5067 | click or scan EU-EC-10011077879 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blindness (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Retinal tear (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5068 | click or scan EU-EC-10011077733 | | 2021-12-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5069 | click or scan EU-EC-10011076560 | | 2021-12-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5070 | click or scan EU-EC-10011076555 | | 2021-12-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5071 | click or scan EU-EC-10011075005 | | 2021-12-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (148d - Fatal - **Results in Death**), Cerebrovascular accident (148d - Fatal - **Results in Death**), Thrombosis (148d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 5072 | click or scan EU-EC-10011075001 | | 2021-12-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5073 | click or scan EU-EC-10011074608 |  | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5074 | click or scan EU-EC-10011074531 |  | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bedridden (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5075 | click or scan EU-EC-10011074479 |  | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Hepatomegaly (n/a - Unknown - ), Hypoaesthesia (n/a - Unknown - ), Lower limb fracture (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5076 | click or scan EU-EC-10011074357 |  | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Increased bronchial secretion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5077 | click or scan EU-EC-10011074202 |  | 2021-12-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Incomplete course of vaccination (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5078 | click or scan EU-EC-10011074202 |  | 2021-12-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Incomplete course of vaccination (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5079 | click or scan EU-EC-10011074193 |  | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5080 | click or scan EU-EC-10011074162 |  | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5081 | click or scan EU-EC-10011074160 |  | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrioventricular dissociation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5082 | click or scan EU-EC-10011074160 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrioventricular dissociation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5083 | click or scan EU-EC-10011074152 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5084 | click or scan EU-EC-10011074151 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5085 | click or scan EU-EC-10011074132 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Influenza (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5086 | click or scan EU-EC-10011074112 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Life Threatening), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5087 | click or scan EU-EC-10011073989 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Oxygen saturation (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5088 | click or scan EU-EC-10011073951 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Monoparesis (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 5089 | click or scan EU-EC-10011073903 | | 2021-12-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (19d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombotic thrombocytopenic purpura (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5090 | click or scan EU-EC-10011073841 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening), Bladder sphincter atony (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Paresis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5091 | click or scan EU-EC-10011073810 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5092 | click or scan EU-EC-10011073745 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5093 | click or scan EU-EC-10011073734 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5094 | click or scan EU-EC-10011073618 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5095 | click or scan EU-EC-10011073269 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5096 | click or scan EU-EC-10011073165 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5097 | click or scan EU-EC-10011073097 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Fatal - **Results in Death**), Poor peripheral circulation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5098 | click or scan EU-EC-10011073094 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5099 | click or scan EU-EC-10011073093 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5100 | click or scan EU-EC-10011072971 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5101 | click or scan EU-EC-10011072611 | | 2021-12-24 | Non Healthcare Professional | EEA | Not Specified | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5102 | click or scan EU-EC-10011072220 | | 2021-12-24 | Healthcare Professional | Non EEA | Not Specified | Male | Brain neoplasm (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5103 | click or scan EU-EC-10011072217 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5104 | click or scan EU-EC-10011072133 | | 2021-12-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Squamous cell carcinoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 5105 | click or scan EU-EC-10011072056 | | 2021-12-24 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5106 | click or scan EU-EC-10011072046 | | 2021-12-24 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| 5107 | click or scan EU-EC-10011072010 | | 2021-12-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 5108 | click or scan EU-EC-10011071987 | | 2021-12-24 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (24d - Fatal - **Results in Death**), Vaccination failure (24d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]) |
| 5109 | click or scan EU-EC-10011071981 | | 2021-12-24 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (12d - Fatal - **Results in Death**), Vaccination failure (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 5110 | click or scan EU-EC-10011071953 | | 2021-12-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 5111 | click or scan EU-EC-10011071930 | | 2021-12-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5112 | click or scan EU-EC-10011071520 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Unknown - ), Cough (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5113 | click or scan EU-EC-10011071471 | | 2021-12-24 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5114 | click or scan EU-EC-10011071296 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5115 | click or scan EU-EC-10011071068 | | 2021-12-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5116 | click or scan EU-EC-10011071029 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Alanine aminotransferase normal (n/a - Fatal - **Results in Death**), Anion gap normal (n/a - Fatal - **Results in Death**), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Basophil count decreased (n/a - Fatal - **Results in Death**), Blood albumin decreased (n/a - Fatal - **Results in Death**), Blood alkaline phosphatase normal (n/a - Fatal - **Results in Death**), Blood bicarbonate normal (n/a - Fatal - **Results in Death**), Blood bilirubin decreased (n/a - Fatal - **Results in Death**), Blood calcium decreased (n/a - Fatal - **Results in Death**), Blood chloride increased (n/a - Fatal - **Results in Death**), Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood gases (n/a - Fatal - **Results in Death**), Blood glucose normal (n/a - Fatal - **Results in Death**), Blood lactic acid decreased (n/a - Fatal - **Results in Death**), Blood osmolarity normal (n/a - Fatal - **Results in Death**), Blood pH normal (n/a - Fatal - **Results in Death**), Blood potassium normal (n/a - Fatal - **Results in Death**), Blood sodium normal (n/a - Fatal - **Results in Death**), Blood urea increased (n/a - Fatal - **Results in Death**), Blood urea nitrogen/creatinine ratio (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Carbon dioxide decreased (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Echocardiogram abnormal (n/a - Fatal - **Results in Death**), Eosinophil count decreased (n/a - Fatal - **Results in Death**), Eosinophil percentage decreased (n/a - Fatal - **Results in Death**), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**), Haematocrit decreased (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Immature granulocyte count (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Lymphocyte count decreased (n/a - Fatal - **Results in Death**), Lymphocyte percentage decreased (n/a - Fatal - **Results in Death**), Mean cell haemoglobin concentration normal (n/a - Fatal - **Results in Death**), Mean cell haemoglobin increased (n/a - Fatal - **Results in Death**), Mean cell volume normal (n/a - Fatal - **Results in Death**), Mean platelet volume normal (n/a - Fatal - **Results in Death**), Monocyte count normal (n/a - Fatal - **Results in Death**), Monocyte percentage (n/a - Fatal - **Results in Death**), Neutrophil count normal (n/a - Fatal - **Results in Death**), Neutrophil percentage increased (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), PCO2 normal (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), Protein total normal (n/a - Fatal - **Results in Death**), Red blood cell count decreased (n/a - Fatal - **Results in Death**), Red blood cell nucleated morphology (n/a - Fatal - **Results in Death**), Red cell distribution width normal (n/a - Fatal - **Results in Death**), Troponin I increased (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), White blood cell count normal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5117 | click or scan EU-EC-10011070931 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Internal haemorrhage (n/a - Fatal - **Results in Death**), Migraine (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5118 | click or scan EU-EC-10011070806 | | 2021-12-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5119 | click or scan EU-EC-10011070742 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5120 | click or scan EU-EC-10011070724 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Unknown - ), Dysphagia (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - ), Insomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - ), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin induration (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5121 | click or scan EU-EC-10011070528 | | 2021-12-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5122 | click or scan EU-EC-10011070220 | | 2021-12-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5123 | click or scan EU-EC-10011070182 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiogram cerebral abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5124 | click or scan EU-EC-10011070021 | | 2021-12-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Arthralgia (3d - Recovered/Resolved - ), COVID-19 (5d - Recovered/Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (3d - Recovered/Resolved - ), Cough (9d - Recovered/Resolved - ), Diarrhoea (4d - Recovered/Resolved - ), Fatigue (5d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Malaise (3d - Recovered/Resolved - ), Myalgia (3d - Recovered/Resolved - ), Nasopharyngitis (9d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5125 | click or scan EU-EC-10011069675 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiomegaly (n/a - Unknown - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericardial haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5126 | click or scan EU-EC-10011069673 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Hepatorenal syndrome (n/a - Fatal - **Results in Death**), International normalised ratio increased (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5127 | click or scan EU-EC-10011069375 | | 2021-12-24 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5128 | click or scan EU-EC-10011069340 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal wall thickening (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Scan abdomen abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5129 | click or scan EU-EC-10011069222 | | 2021-12-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5130 | click or scan EU-EC-10011069196 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5131 | click or scan EU-EC-10011069062 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acquired haemophilia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Unknown - Disabling, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Disabling, Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5132 | click or scan EU-EC-10011068289 | | 2021-12-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5133 | click or scan EU-EC-10011068026 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Interstitial lung disease (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Stress cardiomyopathy (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5134 | click or scan EU-EC-10011068024 | | 2021-12-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5135 | click or scan EU-EC-10011067978 | | 2021-12-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection rupture (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5136 | click or scan EU-EC-10011067457 | | 2021-12-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epistaxis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5137 | click or scan EU-EC-10011067074 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Craniotomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metastases to central nervous system (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5138 | click or scan EU-EC-10011066128 | | 2021-12-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5139 | click or scan EU-EC-10011065795 | | 2021-12-24 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 5140 | click or scan EU-EC-10011065509 | | 2021-12-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Haematology test abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5141 | click or scan EU-EC-10011064854 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) |
| 5142 | click or scan EU-EC-10011064338 | | 2021-12-23 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypopnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiration abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5143 | click or scan EU-EC-10011064328 | | 2021-12-23 | Healthcare Professional | EEA | 65-85 Years | Male | Alveolitis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Interstitial lung disease (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary congestion (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5144 | click or scan EU-EC-10011064228 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5145 | click or scan EU-EC-10011063901 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5146 | click or scan EU-EC-10011063814 |  | 2021-12-23 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 5147 | click or scan EU-EC-10011063741 |  | 2021-12-23 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5148 | click or scan EU-EC-10011063681 |  | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5149 | click or scan EU-EC-10011063607 |  | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Feeling abnormal (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5150 | click or scan EU-EC-10011063592 |  | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5151 | click or scan EU-EC-10011063574 |  | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Blood lactic acid (n/a - Fatal - **Results in Death**), Brain natriuretic peptide (n/a - Fatal - **Results in Death**), C-reactive protein (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Computerised tomogram abdomen (n/a - Fatal - **Results in Death**), Computerised tomogram head (n/a - Fatal - **Results in Death**), Computerised tomogram thorax (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Differential white blood cell count (n/a - Fatal - **Results in Death**), Electrocardiogram (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Fibrin D dimer (n/a - Fatal - **Results in Death**), Full blood count (n/a - Fatal - **Results in Death**), Haematuria (n/a - Fatal - **Results in Death**), Hypoacusis (n/a - Fatal - **Results in Death**), Hypokalaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (n/a - Fatal - **Results in Death**), Influenza A virus test (n/a - Fatal - **Results in Death**), Influenza B virus test (n/a - Fatal - **Results in Death**), Lipase (n/a - Fatal - **Results in Death**), Metabolic function test (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Respiratory syncytial virus test (n/a - Fatal - **Results in Death**), SARS-CoV-2 test (n/a - Fatal - **Results in Death**), Troponin I (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Urine analysis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5152 | click or scan EU-EC-10011063517 | | 2021-12-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 5153 | click or scan EU-EC-10011063481 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5154 | click or scan EU-EC-10011063322 | | 2021-12-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5155 | click or scan EU-EC-10011063239 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5156 | click or scan EU-EC-10011062927 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5157 | click or scan EU-EC-10011062901 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anxiety (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5158 | click or scan EU-EC-10011062477 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Full blood count (n/a - Fatal - **Results in Death**), Metabolic function test (n/a - Fatal - **Results in Death**), Moaning (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5159 | click or scan EU-EC-10011062274 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5160 | click or scan EU-EC-10011062157 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac failure congestive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Gastrointestinal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5161 | click or scan EU-EC-10011062142 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 5162 | click or scan EU-EC-10011061873 | | 2021-12-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening), Dysphagia (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5163 | click or scan EU-EC-10011061787 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5164 | click or scan EU-EC-10011061786 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5165 | click or scan EU-EC-10011061618 | | 2021-12-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Chest pain (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5166 | click or scan EU-EC-10011061605 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Immunisation (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 5167 | click or scan EU-EC-10011061384 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5168 | click or scan EU-EC-10011061074 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cytomegalovirus infection reactivation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5169 | click or scan EU-EC-10011060880 | | 2021-12-23 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5170 | click or scan EU-EC-10011060849 | | 2021-12-23 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5171 | click or scan EU-EC-10011060679 | | 2021-12-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5172 | click or scan EU-EC-10011060661 | | 2021-12-23 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5173 | click or scan EU-EC-10011059918 | | 2021-12-23 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [35d - 1 {DF} - Intramuscular]) |
| 5174 | click or scan EU-EC-10011059917 | | 2021-12-23 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5175 | click or scan EU-EC-10011059783 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5176 | click or scan EU-EC-10011059214 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aneurysm repair (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Ear pain (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5177 | click or scan<br>EU-EC-10011059172 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anion gap normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bicarbonate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood chloride normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac telemetry (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Crepitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture urine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Differential white blood cell count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dry skin (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea at rest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glycosylated haemoglobin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inguinal hernia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5178 | click or scan<br>EU-EC-10011058732 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5179 | click or scan<br>EU-EC-10011058727 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5180 | click or scan<br>EU-EC-10011058491 | | 2021-12-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5181 | click or scan EU-EC-10011058459 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac pacemaker insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Catheterisation cardiac abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary angioplasty (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), End stage renal disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Iliac artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Iliac artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sinus arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5182 | click or scan EU-EC-10011058304 | | 2021-12-23 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5183 | click or scan EU-EC-10011058207 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5184 | click or scan EU-EC-10011058204 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5185 | click or scan EU-EC-10011058199 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5186 | click or scan EU-EC-10011058195 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haematemesis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5187 | click or scan EU-EC-10011058032 |  | 2021-12-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5188 | click or scan EU-EC-10011057806 |  | 2021-12-23 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5189 | click or scan EU-EC-10011057779 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5190 | click or scan EU-EC-10011057745 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysstasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - Caused/Prolonged Hospitalisation), Intensive care (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Unknown - Caused/Prolonged Hospitalisation), Wheelchair user (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5191 | click or scan EU-EC-10011057515 |  | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Application site pain (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5192 | click or scan EU-EC-10011057511 |  | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5193 | click or scan EU-EC-10011057415 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 5194 | click or scan EU-EC-10011057349 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5195 | click or scan EU-EC-10011057337 |  | 2021-12-23 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5196 | click or scan EU-EC-10011057103 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5197 | click or scan EU-EC-10011056986 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5198 | click or scan EU-EC-10011056920 | | 2021-12-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5199 | click or scan EU-EC-10011056913 | | 2021-12-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 5200 | click or scan EU-EC-10011056609 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypersensitivity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5201 | click or scan EU-EC-10011056418 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5202 | click or scan EU-EC-10011056010 | | 2021-12-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Peripheral swelling (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5203 | click or scan EU-EC-10011055387 | | 2021-12-23 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral infarction (1d - Fatal - **Results in Death**), Constipation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Eye pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ileal gangrene (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Metastases to lymph nodes (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (9d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal infarct (9d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal infarct (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Splenic infarction (9d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 5204 | click or scan EU-EC-10011055322 | | 2021-12-23 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 5205 | click or scan EU-EC-10011055314 | | 2021-12-23 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5206 | click or scan EU-EC-10011055310 | | 2021-12-23 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5207 | click or scan EU-EC-10011055303 | | 2021-12-23 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 5208 | click or scan EU-EC-10011055261 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5209 | click or scan EU-EC-10011055255 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5210 | click or scan EU-EC-10011055254 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5211 | click or scan EU-EC-10011055120 | | 2021-12-23 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5212 | click or scan EU-EC-10011055087 | | 2021-12-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiovascular disorder (1d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5213 | click or scan EU-EC-10011055000 | | 2021-12-23 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5214 | click or scan EU-EC-10011054933 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5215 | click or scan EU-EC-10011054737 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vertebral artery dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5216 | click or scan EU-EC-10011054721 | | 2021-12-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delusion (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5217 | click or scan EU-EC-10011054461 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5218 | click or scan EU-EC-10011054408 | | 2021-12-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5219 | click or scan EU-EC-10011054303 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5220 | click or scan EU-EC-10011054302 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5221 | click or scan EU-EC-10011054300 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Face oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5222 | click or scan EU-EC-10011054098 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**), Laboratory test abnormal (n/a - Fatal - **Results in Death**), Thrombectomy (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5223 | click or scan EU-EC-10011054024 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5224 | click or scan EU-EC-10011053827 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sedation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin ulcer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ulcer haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Varicose vein (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Venous ulcer pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5225 | click or scan EU-EC-10011053785 | | 2021-12-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5226 | click or scan EU-EC-10011053723 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Anuria (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5227 | click or scan EU-EC-10011053657 | | 2021-12-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5228 | click or scan EU-EC-10011053583 | | 2021-12-23 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5229 | click or scan EU-EC-10011053569 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram spine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lumbar puncture abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumatosis intestinalis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcal infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Xanthochromia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5230 | click or scan EU-EC-10011053344 | | 2021-12-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5231 | click or scan EU-EC-10011053129 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Prone position (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5232 | click or scan EU-EC-10011053058 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5233 | click or scan EU-EC-10011052953 |  | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apnoea (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Discomfort (n/a - Unknown - Life Threatening), Hyperhidrosis (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5234 | click or scan EU-EC-10011052936 |  | 2021-12-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5235 | click or scan EU-EC-10011052879 |  | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood culture negative (n/a - Fatal - **Results in Death**), Culture urine negative (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Full blood count normal (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Metabolic function test normal (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Skin warm (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Urine analysis normal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5236 | click or scan EU-EC-10011052846 |  | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (2d - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5237 | click or scan EU-EC-10011052823 |  | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Product use issue (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [1d - n/a - Unknown]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Influenza immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5238 | click or scan EU-EC-10011052800 |  | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5239 | click or scan EU-EC-10011052593 |  | 2021-12-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Subcutaneous]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5240 | click or scan EU-EC-10011052557 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood glucose increased (1d - Fatal - **Results in Death**), Breath sounds absent (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Cardioversion (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Resuscitation (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5241 | click or scan EU-EC-10011052535 | | 2021-12-23 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5242 | click or scan EU-EC-10011052496 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5243 | click or scan EU-EC-10011052376 | | 2021-12-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5244 | click or scan EU-EC-10011052365 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 5245 | click or scan EU-EC-10011052348 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5246 | click or scan EU-EC-10011052256 | | 2021-12-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abnormal loss of weight (n/a - Unknown - Other Medically Important Condition), Anaemia (n/a - Unknown - Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Malaise (1wk - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**), Organ failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5247 | click or scan EU-EC-10011051966 | | 2021-12-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Coordination abnormal (76d - Fatal - **Results in Death**), Dyskinesia (76d - Fatal - **Results in Death**), Gait disturbance (76d - Fatal - **Results in Death**), Hypoaesthesia (76d - Fatal - **Results in Death**), Paraesthesia (76d - Fatal - **Results in Death**), Pyrexia (76d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5248 | click or scan EU-EC-10011051167 | | 2021-12-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cystic fibrosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5249 | click or scan EU-EC-10011050894 | | 2021-12-22 | Healthcare Professional | Non EEA | Not Specified | Female | Cognitive disorder (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypersomnia (n/a - Fatal - **Results in Death**), Indifference (n/a - Fatal - **Results in Death**), Neurological decompensation (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5250 | click or scan EU-EC-10011050720 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **5251** | click or scan EU-EC-10011050675 |  | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **5252** | click or scan EU-EC-10011050587 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **5253** | click or scan EU-EC-10011050562 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal X-ray (n/a - Fatal - **Results in Death**), Blood chloride increased (n/a - Fatal - **Results in Death**), Blood glucose normal (n/a - Fatal - **Results in Death**), Blood sodium increased (n/a - Fatal - **Results in Death**), Blood urea increased (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Glomerular filtration rate (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Mean cell haemoglobin concentration decreased (n/a - Fatal - **Results in Death**), Metabolic function test abnormal (n/a - Fatal - **Results in Death**), Nephrolithiasis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Red cell distribution width increased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **5254** | click or scan EU-EC-10011050510 |  | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chronic respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **5255** | click or scan EU-EC-10011049830 |  | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle twitching (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **5256** | click or scan EU-EC-10011049692 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypersensitivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **5257** | click or scan EU-EC-10011049683 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anosmia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **5258** | click or scan EU-EC-10011049571 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5259 | click or scan EU-EC-10011049494 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | CSF oligoclonal band present (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), CSF test abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electromyogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammatory marker increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Motor neurone disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nerve conduction studies abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5260 | click or scan EU-EC-10011049194 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Blood glucose increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**), Lung infiltration (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Polyuria (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), Procalcitonin increased (n/a - Fatal - **Results in Death**), Pulmonary imaging procedure abnormal (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5261 | click or scan EU-EC-10011048581 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5262 | click or scan EU-EC-10011048296 | | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Diabetes mellitus (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5263 | click or scan EU-EC-10011048292 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5264 | click or scan EU-EC-10011048171 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Depression (n/a - Fatal - **Results in Death**), Toxicologic test (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5265 | click or scan EU-EC-10011048002 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5266 | click or scan EU-EC-10011047998 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5267 | click or scan EU-EC-10011047972 | | 2021-12-22 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Upper limb fracture (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5268 | click or scan EU-EC-10011047950 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**), Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5269 | click or scan EU-EC-10011047691 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5270 | click or scan EU-EC-10011047673 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5271 | click or scan EU-EC-10011047478 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral ventricular rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5272 | click or scan EU-EC-10011047382 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5273 | click or scan EU-EC-10011047260 | | 2021-12-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Palpitations (n/a - Unknown - ), Tachycardia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 5274 | click or scan EU-EC-10011047239 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5275 | click or scan EU-EC-10011047203 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 5276 | click or scan EU-EC-10011047198 | | 2021-12-22 | Healthcare Professional | EEA | 18-64 Years | Female | Hypopituitarism (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5277 | click or scan EU-EC-10011047179 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5278 | click or scan EU-EC-10011047073 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5279 | click or scan EU-EC-10011047069 | | 2021-12-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5280 | click or scan EU-EC-10011046962 | | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5281 | click or scan EU-EC-10011046667 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (1d - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5282 | click or scan EU-EC-10011046648 | | 2021-12-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5283 | click or scan EU-EC-10011046570 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bladder catheterisation (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neurogenic bladder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urine analysis normal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5284 | click or scan EU-EC-10011046546 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5285 | click or scan EU-EC-10011046510 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5286 | click or scan EU-EC-10011046499 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pain in extremity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5287 | click or scan EU-EC-10011046445 | | 2021-12-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5288 | click or scan EU-EC-10011046405 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5289 | click or scan EU-EC-10011046282 | | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5290 | click or scan EU-EC-10011045599 | | 2021-12-22 | Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5291 | click or scan EU-EC-10011045592 | | 2021-12-22 | Healthcare Professional | EEA | Not Specified | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5292 | click or scan EU-EC-10011045567 | | 2021-12-22 | Healthcare Professional | EEA | Not Specified | Not Specified | Abortion induced (n/a - Fatal - **Results in Death**, Congenital Anomaly), Aorta hypoplasia (n/a - Fatal - **Results in Death**, Congenital Anomaly), Univentricular heart (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Transplacental]) |
| 5293 | click or scan EU-EC-10011045471 | | 2021-12-22 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [21d - 2 {DF} - Intramuscular]) |
| 5294 | click or scan EU-EC-10011045457 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5295 | click or scan EU-EC-10011045349 | | 2021-12-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5296 | click or scan EU-EC-10011045047 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5297 | click or scan EU-EC-10011045016 | | 2021-12-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Feeling abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5298 | click or scan EU-EC-10011044943 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood sodium abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5299 | click or scan EU-EC-10011044871 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5300 | click or scan EU-EC-10011044755 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5301 | click or scan EU-EC-10011044593 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5302 | click or scan EU-EC-10011044585 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5303 | click or scan EU-EC-10011044584 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5304 | click or scan EU-EC-10011044561 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5305 | click or scan EU-EC-10011044559 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5306 | click or scan EU-EC-10011044522 | | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5307 | click or scan EU-EC-10011044500 | | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5308 | click or scan EU-EC-10011044484 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5309 | click or scan EU-EC-10011044410 | | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic cerebral infarction (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5310 | click or scan EU-EC-10011044188 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (7d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5311 | click or scan EU-EC-10011044121 | | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5312 | click or scan EU-EC-10011044100 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5313 | click or scan EU-EC-10011044099 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5314 | click or scan EU-EC-10011044098 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5315 | click or scan EU-EC-10011044091 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5316 | click or scan EU-EC-10011044085 | | 2021-12-22 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5317 | click or scan EU-EC-10011044025 | | 2021-12-22 | Healthcare Professional | EEA | Not Specified | Male | Cardiovascular symptom (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5318 | click or scan EU-EC-10011043990 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5319 | click or scan EU-EC-10011043952 | | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5320 | click or scan EU-EC-10011043893 |  | 2021-12-22 | Healthcare Professional | EEA | 18-64 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriovenous fistula maturation failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hyperlipidaemia (n/a - Fatal - **Results in Death**), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Noninfective encephalitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory depression (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic vein thrombosis (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vision blurred (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Visual impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 5321 | click or scan EU-EC-10011043869 |  | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 immunisation (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5322 | click or scan EU-EC-10011043758 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Endotracheal intubation (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5323 | click or scan EU-EC-10011043725 |  | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5324 | click or scan EU-EC-10011043710 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 RNA (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5325 | click or scan EU-EC-10011043502 |  | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5326 | click or scan EU-EC-10011043489 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Erythema (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Skin warm (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Other]) |
| 5327 | click or scan EU-EC-10011043464 | | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5328 | click or scan EU-EC-10011043269 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central nervous system necrosis (n/a - Fatal - **Results in Death**), Cerebellar infarction (n/a - Fatal - **Results in Death**), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Hypotonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**), Quadriplegia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 5329 | click or scan EU-EC-10011043052 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5330 | click or scan EU-EC-10011042703 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5331 | click or scan EU-EC-10011042649 | | 2021-12-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5332 | click or scan EU-EC-10011041648 | | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - n/a - n/a - [1d - n/a - n/a]) |
| 5333 | click or scan EU-EC-10011041112 | | 2021-12-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Intracranial aneurysm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5334 | click or scan EU-EC-10011041109 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (7d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5335 | click or scan EU-EC-10011040963 | | 2021-12-22 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5336 | click or scan EU-EC-10011040928 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Right ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin abrasion (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Unknown - Other Medically Important Condition), Traumatic haematoma (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 5337 | click or scan EU-EC-10011040726 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5338 | click or scan EU-EC-10011040720 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Male | Organising pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B)] (S - Influenza immunisation - Dose not changed - [n/a - n/a - Intramuscular]) |
| 5339 | click or scan EU-EC-10011040548 | | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 5340 | click or scan EU-EC-10011040518 | | 2021-12-22 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5341 | click or scan EU-EC-10011040414 |  | 2021-12-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Blood pressure increased (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 5342 | click or scan EU-EC-10011040346 |  | 2021-12-22 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5343 | click or scan EU-EC-10011040213 |  | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5344 | click or scan EU-EC-10011040180 |  | 2021-12-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Malaise (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5345 | click or scan EU-EC-10011040039 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5346 | click or scan EU-EC-10011039842 |  | 2021-12-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Vaccination site erythema (n/a - Unknown - Other Medically Important Condition), Vaccination site swelling (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5347 | click or scan EU-EC-10011039749 |  | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5348 | click or scan EU-EC-10011039551 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5349 | click or scan EU-EC-10011038928 |  | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5350 | click or scan EU-EC-10011038812 |  | 2021-12-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abnormal behaviour (n/a - Unknown - **Results in Death**), Decubitus ulcer (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5351 | click or scan EU-EC-10011038659 |  | 2021-12-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5352 | click or scan EU-EC-10011038600 |  | 2021-12-22 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5353 | click or scan EU-EC-10011038267 |  | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Unknown - Other Medically Important Condition), Haemorrhage subcutaneous (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Kidney congestion (n/a - Unknown - Other Medically Important Condition), Myocardial fibrosis (n/a - Unknown - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial necrosis (n/a - Unknown - Other Medically Important Condition), Petechiae (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Renal tubular necrosis (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5354 | click or scan EU-EC-10011038174 |  | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5355 | click or scan EU-EC-10011038128 |  | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5356 | click or scan EU-EC-10011037809 |  | 2021-12-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5357 | click or scan EU-EC-10011037797 |  | 2021-12-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5358 | click or scan EU-EC-10011037634 |  | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5359 | click or scan EU-EC-10011037501 |  | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Female | SARS-CoV-2 test positive (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5360 | click or scan EU-EC-10011037463 | | 2021-12-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5361 | click or scan EU-EC-10011037405 | | 2021-12-22 | Healthcare Professional | EEA | More than 85 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5362 | click or scan EU-EC-10011037198 | | 2021-12-22 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (0d - Fatal - **Results in Death**), Headache (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5363 | click or scan EU-EC-10011037133 | | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 5364 | click or scan EU-EC-10011036693 | | 2021-12-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ascites (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5365 | click or scan EU-EC-10011036635 | | 2021-12-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5366 | click or scan EU-EC-10011036447 | | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5367 | click or scan EU-EC-10011036302 | | 2021-12-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5368 | click or scan EU-EC-10011036199 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5369 | click or scan EU-EC-10011035985 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5370 | click or scan EU-EC-10011034356 | | 2021-12-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5371 | click or scan EU-EC-10011033603 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Lung adenocarcinoma (n/a - Fatal - **Results in Death**), Metastases to central nervous system (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 5372 | click or scan EU-EC-10011031563 | | 2021-12-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection (n/a - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5373 | click or scan EU-EC-10011031536 | | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 5374 | click or scan EU-EC-10011031501 | | 2021-12-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5375 | click or scan EU-EC-10011031256 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (5d - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Myalgia (5d - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5376 | click or scan EU-EC-10011031004 | | 2021-12-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5377 | click or scan EU-EC-10011030822 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 5378 | click or scan EU-EC-10011030523 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5379 | click or scan EU-EC-10011030384 | | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5380 | click or scan EU-EC-10011030382 | | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5381 | click or scan EU-EC-10011030148 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5382 | click or scan EU-EC-10011030144 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5383 | click or scan EU-EC-10011030135 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hepatic failure (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 5384 | click or scan EU-EC-10011030049 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5385 | click or scan EU-EC-10011029991 | | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5386 | click or scan EU-EC-10011029983 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | Autoimmune hepatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5387 | click or scan EU-EC-10011029817 | | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myalgia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5388 | click or scan EU-EC-10011029811 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Genital haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5389 | click or scan EU-EC-10011029566 |  | 2021-12-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5390 | click or scan EU-EC-10011028773 |  | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | Agranulocytosis (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 5391 | click or scan EU-EC-10011028768 |  | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |
| 5392 | click or scan EU-EC-10011028752 |  | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 5393 | click or scan EU-EC-10011028672 |  | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 5394 | click or scan EU-EC-10011028659 |  | 2021-12-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 5395 | click or scan EU-EC-10011028655 |  | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose reduced - [1d - 1 {DF} - Intramuscular]) |
| 5396 | click or scan EU-EC-10011028594 |  | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 5397 | click or scan EU-EC-10011028581 |  | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (19d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 5398 | click or scan EU-EC-10011028564 |  | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 5399 | click or scan EU-EC-10011028524 |  | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5400 | click or scan EU-EC-10011028355 | | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5401 | click or scan EU-EC-10011028169 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Activated partial thromboplastin time prolonged (n/a - Unknown - ), Aspartate aminotransferase increased (n/a - Unknown - ), Blood bilirubin increased (n/a - Unknown - Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Unknown - Other Medically Important Condition), Body temperature increased (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Hypokalaemia (n/a - Fatal - **Results in Death**), Hyponatraemia (n/a - Fatal - **Results in Death**), Lipase decreased (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Prothrombin time prolonged (n/a - Unknown - ), White blood cell count decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 5402 | click or scan EU-EC-10011028025 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5403 | click or scan EU-EC-10011027973 | | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Female | Stillbirth (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5404 | click or scan EU-EC-10011027924 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 5405 | click or scan EU-EC-10011027821 | | 2021-12-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5406 | click or scan EU-EC-10011027815 | | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Left ventricular hypertrophy (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5407 | click or scan EU-EC-10011027255 | | 2021-12-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5408 | click or scan EU-EC-10011027200 | | 2021-12-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Agitation (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Musculoskeletal chest pain (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **5409** | click or scan EU-EC-10011027073 | | 2021-12-21 | Non Healthcare Professional | EEA | More than 85 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical condition abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5410** | click or scan EU-EC-10011027058 | | 2021-12-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Blood urine present (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Necrotising fasciitis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5411** | click or scan EU-EC-10011027046 | | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **5412** | click or scan EU-EC-10011027040 | | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5413** | click or scan EU-EC-10011026859 | | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [1d - 1 {DF} - Unknown]) |
| **5414** | click or scan EU-EC-10011026846 | | 2021-12-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal distension (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Amnesia (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Chest discomfort (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dementia (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dysstasia (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Listless (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pain (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Peripheral swelling (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombosis (3mo - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **5415** | click or scan EU-EC-10011026814 | | 2021-12-21 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (1d - Fatal - **Results in Death**), Acute myocardial infarction (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lactic acidosis (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **5416** | click or scan EU-EC-10011026628 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]), VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5417 | click or scan EU-EC-10011026628 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]), VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5418 | click or scan EU-EC-10011026502 | | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Abdominal pain upper (n/a - Unknown - ), Blood potassium decreased (n/a - Unknown - ), Dehydration (n/a - Unknown - ), Fall (n/a - Unknown - ), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (3min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ), Paroxysmal arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Restlessness (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5419 | click or scan EU-EC-10011026207 | | 2021-12-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5420 | click or scan EU-EC-10011025565 | | 2021-12-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5421 | click or scan EU-EC-10011025441 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5422 | click or scan EU-EC-10011025297 | | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5423 | click or scan EU-EC-10011025193 | | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5424 | click or scan EU-EC-10011024973 | | 2021-12-21 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5425 | click or scan EU-EC-10011024576 | | 2021-12-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **5426** | click or scan EU-EC-10011024317 |  | 2021-12-21 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Urosepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **5427** | click or scan EU-EC-10011023783 |  | 2021-12-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **5428** | click or scan EU-EC-10011023069 |  | 2021-12-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary artery thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5429** | click or scan EU-EC-10011023046 |  | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ileus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **5430** | click or scan EU-EC-10011022973 |  | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiovascular disorder (n/a - Unknown - ), Choking sensation (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Hypoventilation (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5431** | click or scan EU-EC-10011022561 |  | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **5432** | click or scan EU-EC-10011021974 |  | 2021-12-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **5433** | click or scan EU-EC-10011021367 |  | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **5434** | click or scan EU-EC-10011021072 |  | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5435 | click or scan EU-EC-10011020835 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5436 | click or scan EU-EC-10011020759 | | 2021-12-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5437 | click or scan EU-EC-10011020635 | | 2021-12-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5438 | click or scan EU-EC-10011020624 | | 2021-12-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5439 | click or scan EU-EC-10011020164 | | 2021-12-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Intestinal infarction (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 5440 | click or scan EU-EC-10011019953 | | 2021-12-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Diabetic coma (n/a - Fatal - **Results in Death**), Full blood count abnormal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5441 | click or scan EU-EC-10011018918 | | 2021-12-20 | Healthcare Professional | Non EEA | Not Specified | Female | Exposure during pregnancy (n/a - Unknown - ), Off label use (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5442 | click or scan EU-EC-10011018692 | | 2021-12-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5443 | click or scan EU-EC-10011018689 | | 2021-12-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5444 | click or scan EU-EC-10011017989 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5445 | click or scan EU-EC-10011017136 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5446 | click or scan EU-EC-10011017124 | | 2021-12-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Bundle branch block left (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fall (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Livedo reticularis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial necrosis marker increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 5447 | click or scan EU-EC-10011016976 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Constipation (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5448 | click or scan EU-EC-10011016780 | | 2021-12-20 | Healthcare Professional | EEA | Not Specified | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5449 | click or scan EU-EC-10011016776 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5450 | click or scan EU-EC-10011016465 | | 2021-12-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Peripheral swelling (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5451 | click or scan EU-EC-10011015942 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5452 | click or scan EU-EC-10011015936 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Nausea (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 5453 | click or scan EU-EC-10011015249 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac flutter (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (2d - Fatal - **Results in Death**), Palpitations (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 5454 | click or scan EU-EC-10011014917 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Agranulocytosis (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5455 | click or scan EU-EC-10011014843 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**), Throat irritation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5456 | click or scan EU-EC-10011014779 | | 2021-12-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (1d - Recovered/Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Unknown - ), Hospitalisation (5d - Not Recovered/Not Resolved - ), Hospitalisation (8d - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Injection site erythema (2d - Recovered/Resolved - ), Injection site inflammation (2d - Recovered/Resolved - ), Injection site pruritus (2d - Recovered/Resolved - ), Injection site warmth (2d - Recovered/Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - ), Retching (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5457 | click or scan EU-EC-10011014293 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5458 | click or scan EU-EC-10011014285 | | 2021-12-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Gait disturbance (n/a - Unknown - ), Motor neurone disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peroneal nerve palsy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5459 | click or scan EU-EC-10011014277 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5460 | click or scan EU-EC-10011014274 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5461 | click or scan EU-EC-10011014271 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5462 | click or scan EU-EC-10011014270 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Recovered/Resolved - ), COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nuchal rigidity (n/a - Recovered/Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5463 | click or scan EU-EC-10011014076 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5464 | click or scan EU-EC-10011013931 | | 2021-12-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5465 | click or scan EU-EC-10011013871 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5466 | click or scan EU-EC-10011013576 |  | 2021-12-20 | Healthcare Professional | EEA | More than 85 Years | Female | Pleurisy (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5467 | click or scan EU-EC-10011013307 |  | 2021-12-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arterial rupture (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Eye haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Fatal - **Results in Death**), Meningorrhagia (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 5468 | click or scan EU-EC-10011013215 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 5469 | click or scan EU-EC-10011013204 |  | 2021-12-20 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5470 | click or scan EU-EC-10011013153 |  | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Abortion induced (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5471 | click or scan EU-EC-10011013133 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 5472 | click or scan EU-EC-10011013071 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5473 | click or scan EU-EC-10011013069 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5474 | click or scan EU-EC-10011013038 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiogenic shock (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5475 | click or scan EU-EC-10011013011 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5476 | click or scan EU-EC-10011013010 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5477 | click or scan EU-EC-10011012882 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5478 | click or scan EU-EC-10011012881 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5479 | click or scan EU-EC-10011012841 | | 2021-12-20 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cardiac disorder (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure timing unspecified (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 5480 | click or scan EU-EC-10011012809 | | 2021-12-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5481 | click or scan EU-EC-10011012420 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening), Immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5482 | click or scan EU-EC-10011012398 | | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5483 | click or scan EU-EC-10011012376 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5484 | click or scan EU-EC-10011012313 |  | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5485 | click or scan EU-EC-10011012227 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5486 | click or scan EU-EC-10011012053 |  | 2021-12-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5487 | click or scan EU-EC-10011011784 |  | 2021-12-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5488 | click or scan EU-EC-10011011558 |  | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5489 | click or scan EU-EC-10011011549 |  | 2021-12-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5490 | click or scan EU-EC-10011011547 |  | 2021-12-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Psoriasis (n/a - Not Recovered/Not Resolved - ), Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5491 | click or scan EU-EC-10011011541 |  | 2021-12-20 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5492 | click or scan EU-EC-10011011446 |  | 2021-12-20 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5493 | click or scan EU-EC-10011011417 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5494 | click or scan EU-EC-10011011221 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 5495 | click or scan EU-EC-10011011211 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5496 | click or scan EU-EC-10011011197 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anuria (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5497 | click or scan EU-EC-10011011194 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5498 | click or scan EU-EC-10011010959 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Liver disorder (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5499 | click or scan EU-EC-10011010899 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pyrexia (1d - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5500 | click or scan EU-EC-10011010671 | | 2021-12-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Antibody test abnormal (n/a - Not Recovered/Not Resolved - ), Antimitochondrial antibody positive (n/a - Not Recovered/Not Resolved - ), Autoimmune cholangitis (n/a - Unknown - Other Medically Important Condition), Blood disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood immunoglobulin E increased (n/a - Unknown - ), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Cytopenia (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dyskinesia (n/a - Unknown - ), Electrolyte imbalance (n/a - Unknown - ), Eosinophil count increased (n/a - Unknown - ), Escherichia urinary tract infection (n/a - Unknown - Other Medically Important Condition), Feeding disorder (n/a - Unknown - ), Hepatic function abnormal (n/a - Not Recovered/Not Resolved - ), Hypercapnia (n/a - Unknown - ), Lacunar infarction (n/a - Unknown - Other Medically Important Condition), Liver disorder (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Performance status decreased (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Purpura (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ), Splenomegaly (n/a - Unknown - ), Staphylococcal bacteraemia (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Type I hypersensitivity (n/a - Unknown - Other Medically Important Condition), Type IV hypersensitivity reaction (n/a - Unknown - ), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5501 | click or scan EU-EC-10011010639 | | 2021-12-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5502 | click or scan EU-EC-10011010509 | | 2021-12-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Amyloidosis (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Nephrotic syndrome (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [82d - n/a - Intramuscular]) |
| 5503 | click or scan EU-EC-10011010478 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral ischaemia (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5504 | click or scan EU-EC-10011010436 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5505 | click or scan EU-EC-10011010429 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5506 | click or scan EU-EC-10011010339 | | 2021-12-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Hypotension (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5507 | click or scan EU-EC-10011010187 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5508 | click or scan EU-EC-10011010140 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5509 | click or scan EU-EC-10011010125 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5510 | click or scan EU-EC-10011009981 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Administration site pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paresis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5511 | click or scan EU-EC-10011009972 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5512 | click or scan EU-EC-10011009898 | | 2021-12-20 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Unknown - ), Parkinson's disease (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5513 | click or scan EU-EC-10011009879 | | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5514 | click or scan EU-EC-10011009829 | | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Disorientation (n/a - Not Recovered/Not Resolved - ), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5515 | click or scan EU-EC-10011009535 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - ), Generalised tonic-clonic seizure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic transformation stroke (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - ), Immune thrombocytopenia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - ), Mydriasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Superior sagittal sinus thrombosis (5d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 5516 | click or scan EU-EC-10011009376 | | 2021-12-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Arthritis (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dizziness (2d - Recovered/Resolved - ), Dry eye (n/a - Unknown - ), Headache (n/a - Unknown - ), Leukaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Muscle spasms (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ), Nausea (2d - Recovered/Resolved - ), Stomatitis (n/a - Unknown - ), Suspected COVID-19 (n/a - Unknown - ), Tinnitus (n/a - Unknown - ), Vertigo (2d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5517 | click or scan EU-EC-10011009340 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5518 | click or scan EU-EC-10011009339 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pallor (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5519 | click or scan EU-EC-10011009335 |  | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (0min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5520 | click or scan EU-EC-10011009279 |  | 2021-12-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blindness (n/a - Not Recovered/Not Resolved - Disabling), Condition aggravated (n/a - Not Recovered/Not Resolved - Disabling), Corneal graft rejection (n/a - Not Recovered/Not Resolved - Disabling), Cystoid macular oedema (n/a - Not Recovered/Not Resolved - Disabling), Keratic precipitates (n/a - Not Recovered/Not Resolved - Disabling), Lacrimation increased (n/a - Not Recovered/Not Resolved - Disabling), Photophobia (n/a - Not Recovered/Not Resolved - Disabling), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5521 | click or scan EU-EC-10011009245 |  | 2021-12-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5522 | click or scan EU-EC-10011009239 |  | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cavernous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemianaesthesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ), Photophobia (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [DYDROGESTERONE] (S - Ovarian cyst - n/a - [1d - 10mg - Oral]), [ESTRADIOL HEMIHYDRATE, ESTRADIOL VALERATE] (S - Ovarian cyst - Not applicable - [1d - 2mg - Oral]) |
| 5523 | click or scan EU-EC-10011009233 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5524 | click or scan EU-EC-10011009211 |  | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Carotid artery thrombosis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haematoma (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Transverse sinus thrombosis (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]) |
| 5525 | click or scan EU-EC-10011008981 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation, Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5526 | click or scan EU-EC-10011008818 |  | 2021-12-20 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5527 | click or scan EU-EC-10011008801 | | 2021-12-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5528 | click or scan EU-EC-10011008530 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5529 | click or scan EU-EC-10011007952 | | 2021-12-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5530 | click or scan EU-EC-10011007707 | | 2021-12-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5531 | click or scan EU-EC-10011007392 | | 2021-12-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 5532 | click or scan EU-EC-10011007382 | | 2021-12-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Cerebrovascular disorder (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**, Disabling), Platelet count decreased (n/a - Unknown - Disabling), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5533 | click or scan EU-EC-10011007034 | | 2021-12-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blood glucose increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetic hyperosmolar coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematocrit abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nephropathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5534 | click or scan EU-EC-10011006712 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5535 | click or scan EU-EC-10011006550 | | 2021-12-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 5536 | click or scan EU-EC-10011006238 | | 2021-12-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5537 | click or scan EU-EC-10011006139 | | 2021-12-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5538 | click or scan EU-EC-10011006137 | | 2021-12-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5539 | click or scan EU-EC-10011005754 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), No reaction on previous exposure to drug (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1 d - n/a - Intramuscular]) |
| 5540 | click or scan EU-EC-10011005731 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Febrile convulsion (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5541 | click or scan EU-EC-10011005446 | | 2021-12-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5542 | click or scan EU-EC-10011005246 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Generalised oedema (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 5543 | click or scan EU-EC-10011005131 | | 2021-12-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5544 | click or scan EU-EC-10011005029 | | 2021-12-20 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5545 | click or scan EU-EC-10011005003 | | 2021-12-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5546 | click or scan EU-EC-10011004188 | | 2021-12-19 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 5547 | click or scan EU-EC-10011003936 | | 2021-12-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pharyngitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5548 | click or scan EU-EC-10011003417 | | 2021-12-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 5549 | click or scan EU-EC-10011003266 | | 2021-12-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pain in extremity (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5550 | click or scan EU-EC-10011003038 | | 2021-12-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5551 | click or scan EU-EC-10011002871 | | 2021-12-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5552 | click or scan EU-EC-10011002158 | | 2021-12-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), NOT AVAILABLE [BNT 162] (S - Immunisation - n/a - [n/a - n/a - Unknown]), NOT AVAILABLE [BNT 162] (S - n/a - n/a - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5553 | click or scan EU-EC-10011001937 | | 2021-12-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5554 | click or scan EU-EC-10011001143 | | 2021-12-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - Unknown]) |
| 5555 | click or scan EU-EC-10011001141 | | 2021-12-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Not Recovered/Not Resolved - ), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haematological malignancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - Unknown]) |
| 5556 | click or scan EU-EC-10011000771 | | 2021-12-18 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (7d - Fatal - **Results in Death**), Azotaemia (7d - Fatal - **Results in Death**), Creatinine renal clearance increased (7d - Fatal - **Results in Death**), Culture urine positive (7d - Fatal - **Results in Death**), Decreased appetite (7d - Fatal - **Results in Death**), Electrolyte imbalance (7d - Fatal - **Results in Death**), Pyrexia (7d - Fatal - **Results in Death**), Sepsis (7d - Fatal - **Results in Death**), Transaminases increased (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), FLUAD TETRA [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5557 | click or scan EU-EC-10011000191 | | 2021-12-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5558 | click or scan EU-EC-10011000126 | | 2021-12-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypothyroidism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5559 | click or scan EU-EC-10010999809 | | 2021-12-17 | Healthcare Professional | EEA | Not Specified | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5560 | click or scan EU-EC-10010999658 | | 2021-12-17 | Healthcare Professional | Non EEA | Not Specified | Female | Blood urine present (n/a - Unknown - ), Concomitant disease progression (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5561 | click or scan EU-EC-10010999330 | | 2021-12-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5562 | click or scan EU-EC-10010999251 |  | 2021-12-17 | Healthcare Professional | EEA | More than 85 Years | Female | Pericarditis (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), [B/BRISBANE/60/2008-LIKE VIRUS, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)-DERIVED STRAIN USED NYMC X-181, SORBITAN TRIOLEATE, POLYSORBATE 80, SODIUM CITRATE, A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/GUANDONG-MAONAN/SWL1536/2019 (H1N1)PDM09-LIKE VIRUS (A/VICTORIA/2454/2019 IVR-207), SQUALENE, CITRIC ACID, SORBITAN TRIOLEATE, POLYSORBATE 80, SODIUM CITRATE, CITRIC ACID ANHYDROUS, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/BRISBANE/9/2014 (WILD TYPE), SQUALENE, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181)] (S - Influenza immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 5563 | click or scan EU-EC-10010999117 |  | 2021-12-17 | Healthcare Professional | EEA | 18-64 Years | Female | Glomerulonephritis rapidly progressive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Systemic lupus erythematosus (86d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5564 | click or scan EU-EC-10010998998 |  | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Encephalitis (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) |
| 5565 | click or scan EU-EC-10010998364 |  | 2021-12-17 | Healthcare Professional | EEA | 18-64 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Giant cell myocarditis (n/a - Fatal - **Results in Death**), Hyperthyroidism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5566 | click or scan EU-EC-10010998232 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **5567** | click or scan<br><br>EU-EC-10010998207 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]), [B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **5568** | click or scan<br><br>EU-EC-10010997985 | | 2021-12-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5569 | click or scan EU-EC-10010997782 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5570 | click or scan EU-EC-10010997721 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Male | Hypercalcaemia (n/a - Fatal - **Results in Death**), Inflammation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5571 | click or scan EU-EC-10010997670 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5572 | click or scan EU-EC-10010997670 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5573 | click or scan EU-EC-10010997655 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Lymphocytic infiltration (n/a - Fatal - **Results in Death**), Physical deconditioning (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Vertebral artery dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5574 | click or scan EU-EC-10010997627 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Unknown - Life Threatening), Malaise (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5575 | click or scan EU-EC-10010997549 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Paraesthesia (n/a - Fatal - **Results in Death**), Peripheral sensory neuropathy (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5576 | click or scan EU-EC-10010997449 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5577 | click or scan EU-EC-10010997418 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5578 | click or scan EU-EC-10010997337 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5579 | click or scan EU-EC-10010997158 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5580 | click or scan EU-EC-10010996757 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Eye swelling (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Malaise (n/a - Unknown - ), Metastatic lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - ), Swelling face (n/a - Unknown - ), Vaccination site erythema (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5581 | click or scan EU-EC-10010996569 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Injection site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5582 | click or scan EU-EC-10010996566 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Eye pain (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Ophthalmoplegia (n/a - Recovering/Resolving - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5583 | click or scan EU-EC-10010996528 | | 2021-12-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5584 | click or scan EU-EC-10010996508 | | 2021-12-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Chest pain (3d - Fatal - **Results in Death**), Circulatory collapse (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 5585 | click or scan EU-EC-10010996505 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5586 | click or scan EU-EC-10010996391 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Life Threatening), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 5587 | click or scan EU-EC-10010996207 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Lethargy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5588 | click or scan EU-EC-10010996190 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5589 | click or scan EU-EC-10010995717 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Lethargy (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5590 | click or scan EU-EC-10010995417 | | 2021-12-17 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 5591 | click or scan EU-EC-10010995362 | | 2021-12-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [21d - 1 {DF} - Intramuscular]) |
| 5592 | click or scan EU-EC-10010995153 | | 2021-12-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 5593 | click or scan EU-EC-10010995118 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Illness (n/a - Unknown - ), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5594 | click or scan EU-EC-10010994836 | | 2021-12-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaphylactic shock (n/a - Unknown - Other Medically Important Condition), Aspartate aminotransferase increased (n/a - Unknown - ), Asthma (n/a - Recovered/Resolved - Life Threatening), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Cardiac failure chronic (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Coronary artery thrombosis (n/a - Unknown - Other Medically Important Condition), Delirium (n/a - Unknown - Other Medically Important Condition), Eyelid oedema (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Infection (n/a - Unknown - ), Kounis syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Obstructive airways disorder (1h - Recovered/Resolved - ), Pleural effusion (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Respiratory tract infection bacterial (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5595 | click or scan EU-EC-10010994829 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5596 | click or scan EU-EC-10010994822 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5597 | click or scan EU-EC-10010994817 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5598 | click or scan EU-EC-10010994815 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arterial thrombosis (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5599 | click or scan EU-EC-10010994814 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5600 | click or scan EU-EC-10010994804 | | 2021-12-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5601 | click or scan EU-EC-10010994783 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Faeces discoloured (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5602 | click or scan EU-EC-10010994777 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Arthralgia (n/a - Unknown - ), Cardiac infection (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Unknown - ), Loss of consciousness (1d - Fatal - **Results in Death**), Muscle twitching (n/a - Unknown - ), Nausea (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Unknown - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5603 | click or scan EU-EC-10010994764 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Intracranial aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5604 | click or scan EU-EC-10010994753 | | 2021-12-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Brain death (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5605 | click or scan EU-EC-10010994747 | | 2021-12-17 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Maternal exposure timing unspecified (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 5606 | click or scan EU-EC-10010994650 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5607 | click or scan EU-EC-10010994634 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Metastases to liver (n/a - Unknown - Other Medically Important Condition), Pancreatic carcinoma (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 5608 | click or scan EU-EC-10010994412 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Limb discomfort (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5609 | click or scan EU-EC-10010994408 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Haemorrhage in pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5610 | click or scan EU-EC-10010994408 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Haemorrhage in pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5611 | click or scan EU-EC-10010994222 |  | 2021-12-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Dementia (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Parkinson's disease (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5612 | click or scan EU-EC-10010993943 |  | 2021-12-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5613 | click or scan EU-EC-10010993933 |  | 2021-12-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5614 | click or scan EU-EC-10010993932 |  | 2021-12-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5615 | click or scan EU-EC-10010993901 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Peritonitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 5616 | click or scan EU-EC-10010993889 |  | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5617 | click or scan EU-EC-10010993768 |  | 2021-12-17 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5618 | click or scan EU-EC-10010993624 |  | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse reaction (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5619 | click or scan EU-EC-10010993481 |  | 2021-12-17 | Healthcare Professional | EEA | More than 85 Years | Male | Ventricular fibrillation (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5620 | click or scan EU-EC-10010993139 |  | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 5621 | click or scan EU-EC-10010993113 |  | 2021-12-17 | Healthcare Professional | EEA | Not Specified | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 5622 | click or scan EU-EC-10010993095 |  | 2021-12-17 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5623 | click or scan EU-EC-10010993063 |  | 2021-12-17 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5624 | click or scan EU-EC-10010993062 |  | 2021-12-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5625 | click or scan EU-EC-10010993060 |  | 2021-12-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Headache (n/a - Not Recovered/Not Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5626 | click or scan EU-EC-10010993057 |  | 2021-12-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5627 | click or scan EU-EC-10010993044 |  | 2021-12-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Seizure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5628 | click or scan EU-EC-10010992989 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash erythematous (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5629 | click or scan EU-EC-10010992873 |  | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Albumin globulin ratio (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5630 | click or scan EU-EC-10010992525 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5631 | click or scan EU-EC-10010992478 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5632 | click or scan EU-EC-10010992279 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5633 | click or scan EU-EC-10010992211 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5634 | click or scan EU-EC-10010992008 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Essential hypertension (n/a - Fatal - **Results in Death**), Mental disorder (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5635 | click or scan EU-EC-10010991974 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5636 | click or scan EU-EC-10010991967 | | 2021-12-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Skin haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5637 | click or scan EU-EC-10010991422 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5638 | click or scan EU-EC-10010991302 | | 2021-12-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5639 | click or scan EU-EC-10010991264 |  | 2021-12-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Psychomotor hyperactivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5640 | click or scan EU-EC-10010991176 |  | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 5641 | click or scan EU-EC-10010991053 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5642 | click or scan EU-EC-10010991051 |  | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5643 | click or scan EU-EC-10010990651 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5644 | click or scan EU-EC-10010990602 |  | 2021-12-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5645 | click or scan EU-EC-10010990560 |  | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5646 | click or scan EU-EC-10010990359 |  | 2021-12-17 | Non Healthcare Professional | EEA | Not Specified | Female | Pancreatitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5647 | click or scan EU-EC-10010990338 |  | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5648 | click or scan EU-EC-10010990328 |  | 2021-12-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **5649** | click or scan EU-EC-10010990325 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **5650** | click or scan EU-EC-10010990304 | | 2021-12-17 | Non Healthcare Professional | EEA | Not Specified | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **5651** | click or scan EU-EC-10010990066 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **5652** | click or scan EU-EC-10010990065 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **5653** | click or scan EU-EC-10010989994 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **5654** | click or scan EU-EC-10010989716 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5655** | click or scan EU-EC-10010989713 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Ascites (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Hepatic enzyme increased (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5656** | click or scan EU-EC-10010989711 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5657** | click or scan EU-EC-10010989710 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5658** | click or scan EU-EC-10010989687 | | 2021-12-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Throat tightness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **5659** | click or scan EU-EC-10010989616 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **5660** | click or scan EU-EC-10010989592 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5{DF} - Unknown - More in ICSR]) |
| **5661** | click or scan EU-EC-10010989336 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5662** | click or scan EU-EC-10010989328 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **5663** | click or scan EU-EC-10010989210 | | 2021-12-17 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Pelvic venous thrombosis (n/a - Unknown - Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **5664** | click or scan EU-EC-10010989013 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (14d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (14d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (14d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (14d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (14d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Palliative care (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Superinfection bacterial (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (14d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **5665** | click or scan EU-EC-10010988999 | | 2021-12-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspepsia (n/a - Unknown - Life Threatening), Resuscitation (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **5666** | click or scan EU-EC-10010988902 | | 2021-12-17 | Non Healthcare Professional | EEA | Not Specified | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **5667** | click or scan EU-EC-10010988900 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **5668** | click or scan EU-EC-10010988832 | | 2021-12-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Renal injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5669 | click or scan EU-EC-10010988678 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5670 | click or scan EU-EC-10010988671 | | 2021-12-17 | Healthcare Professional | EEA | Not Specified | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5671 | click or scan EU-EC-10010988644 | | 2021-12-17 | Non Healthcare Professional | EEA | Not Specified | Female | Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5672 | click or scan EU-EC-10010988643 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5673 | click or scan EU-EC-10010988635 | | 2021-12-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5674 | click or scan EU-EC-10010988626 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5675 | click or scan EU-EC-10010988612 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5676 | click or scan EU-EC-10010988434 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 5677 | click or scan EU-EC-10010988349 | | 2021-12-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5678 | click or scan EU-EC-10010988291 | | 2021-12-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5679 | click or scan EU-EC-10010988130 | | 2021-12-17 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**), Renal failure (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5680 | click or scan EU-EC-10010988013 | | 2021-12-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardio-respiratory distress (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Migraine (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5681 | click or scan EU-EC-10010986950 | | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5682 | click or scan EU-EC-10010986878 | | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Female | Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5683 | click or scan EU-EC-10010986847 | | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Male | Anuria (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fournier's gangrene (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Necrotising fasciitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Scrotal erythema (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Scrotal pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Scrotal swelling (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5684 | click or scan EU-EC-10010986272 | | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 5685 | click or scan EU-EC-10010986175 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5686 | click or scan EU-EC-10010985692 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5687 | click or scan EU-EC-10010985629 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5688 | click or scan EU-EC-10010985437 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5689 | click or scan EU-EC-10010985245 |  | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5690 | click or scan EU-EC-10010985181 |  | 2021-12-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5691 | click or scan EU-EC-10010985063 |  | 2021-12-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5692 | click or scan EU-EC-10010984948 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5693 | click or scan EU-EC-10010984752 |  | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5694 | click or scan EU-EC-10010984587 |  | 2021-12-16 | Healthcare Professional | EEA | More than 85 Years | Female | Infection (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5695 | click or scan EU-EC-10010984526 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Capillary leak syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Distributive shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Polymerase chain reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5696 | click or scan EU-EC-10010984497 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5697 | click or scan EU-EC-10010984255 | | 2021-12-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5698 | click or scan EU-EC-10010984003 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5699 | click or scan EU-EC-10010983876 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriosclerosis (1d - Fatal - **Results in Death**), Diabetes mellitus (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5700 | click or scan EU-EC-10010983866 | | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cold sweat (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diplopia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Transverse sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5701 | click or scan EU-EC-10010983774 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5702 | click or scan EU-EC-10010983578 |  | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemolytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Weight decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5703 | click or scan EU-EC-10010983425 |  | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | Haematoma (122d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 5704 | click or scan EU-EC-10010983363 |  | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5705 | click or scan EU-EC-10010983362 |  | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 5706 | click or scan EU-EC-10010983333 |  | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5707 | click or scan EU-EC-10010983306 |  | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5708 | click or scan EU-EC-10010983296 |  | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5709 | click or scan EU-EC-10010983209 |  | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Life Threatening), Cardiomyopathy (n/a - Fatal - **Results in Death**, Life Threatening), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Chills (n/a - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5710 | click or scan EU-EC-10010983050 |  | 2021-12-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Not Recovered/Not Resolved - ), Abnormal loss of weight (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Petechiae (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5711 | click or scan EU-EC-10010982722 |  | 2021-12-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **5712** | click or scan EU-EC-10010982626 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chronic kidney disease (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **5713** | click or scan EU-EC-10010982603 | | 2021-12-16 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **5714** | click or scan EU-EC-10010982594 | | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [39d - 1 {DF} - Intramuscular]) |
| **5715** | click or scan EU-EC-10010982580 | | 2021-12-16 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **5716** | click or scan EU-EC-10010981945 | | 2021-12-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **5717** | click or scan EU-EC-10010981874 | | 2021-12-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| **5718** | click or scan EU-EC-10010981589 | | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **5719** | click or scan EU-EC-10010980580 | | 2021-12-16 | Non Healthcare Professional | EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **5720** | click or scan EU-EC-10010980170 | | 2021-12-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaginal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **5721** | click or scan EU-EC-10010979967 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5722 | click or scan EU-EC-10010979966 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Headache (3d - Recovered/Resolved - ), Hyperhidrosis (n/a - Fatal - **Results in Death**, Life Threatening), Pain (4d - Recovered/Resolved - ), Pain in extremity (3d - Recovered/Resolved - ), Pallor (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5723 | click or scan EU-EC-10010979962 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5724 | click or scan EU-EC-10010979796 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Headache (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5725 | click or scan EU-EC-10010979743 |  | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cor pulmonale acute (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Microangiopathic haemolytic anaemia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5726 | click or scan EU-EC-10010979620 |  | 2021-12-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Blood glucose decreased (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5727 | click or scan EU-EC-10010979487 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5728 | click or scan EU-EC-10010979187 |  | 2021-12-16 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5729 | click or scan EU-EC-10010978955 |  | 2021-12-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Gait inability (n/a - Unknown - Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5730 | click or scan EU-EC-10010978921 |  | 2021-12-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5731 | click or scan EU-EC-10010978739 |  | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Influenza like illness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5732 | click or scan EU-EC-10010978600 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5733 | click or scan EU-EC-10010978596 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Dysuria (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5734 | click or scan EU-EC-10010978386 | | 2021-12-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Adenomyosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5735 | click or scan EU-EC-10010978379 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Hepatitis B reactivation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 5736 | click or scan EU-EC-10010978356 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5737 | click or scan EU-EC-10010978323 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5738 | click or scan EU-EC-10010978278 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5739 | click or scan EU-EC-10010977887 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5740 | click or scan EU-EC-10010977818 | | 2021-12-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Infection (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5741 | click or scan EU-EC-10010977709 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5742 | click or scan EU-EC-10010977680 | | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Rash erythematous (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5743 | click or scan EU-EC-10010977554 | | 2021-12-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5744 | click or scan EU-EC-10010977406 | | 2021-12-16 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5745 | click or scan EU-EC-10010977121 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Amnesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constipation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal motility disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary retention (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5746 | click or scan EU-EC-10010976662 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anti-neutrophil cytoplasmic antibody positive vasculitis (n/a - Unknown - Other Medically Important Condition), Bundle branch block right (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Unknown - Other Medically Important Condition), Cytomegalovirus test positive (n/a - Unknown - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Unknown - Other Medically Important Condition), Procedural pain (n/a - Unknown - Other Medically Important Condition), Pseudomonas infection (n/a - Unknown - Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Squamous cell carcinoma of the tongue (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5747 | click or scan EU-EC-10010976120 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrooesophageal reflux disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5748 | click or scan EU-EC-10010975915 | | 2021-12-16 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure congestive (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 5749 | click or scan EU-EC-10010975398 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5750 | click or scan EU-EC-10010975327 | | 2021-12-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5751 | click or scan EU-EC-10010975059 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Oxygen saturation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5752 | click or scan EU-EC-10010975043 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ammonia increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram spine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Near death experience (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nonalcoholic fatty liver disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rectal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound kidney (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 5753 | click or scan EU-EC-10010974960 | | 2021-12-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Clostridium difficile infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5754 | click or scan EU-EC-10010974939 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5755 | click or scan EU-EC-10010974623 | | 2021-12-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5756 | click or scan EU-EC-10010974570 | | 2021-12-16 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5757 | click or scan EU-EC-10010974218 | | 2021-12-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5758 | click or scan EU-EC-10010974203 | | 2021-12-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion (4d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Incorrect route of product administration (n/a - Unknown - ), Medication error (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - Subcutaneous]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Subcutaneous]) |
| 5759 | click or scan EU-EC-10010973701 | | 2021-12-16 | Healthcare Professional | EEA | 18-64 Years | Male | Thrombotic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5760 | click or scan EU-EC-10010973694 | | 2021-12-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5761 | click or scan EU-EC-10010973633 | | 2021-12-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Infarction (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**), Syncope (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 5762 | click or scan EU-EC-10010972722 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5763 | click or scan EU-EC-10010972672 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5764 | click or scan EU-EC-10010972332 | | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 5765 | click or scan EU-EC-10010972319 | | 2021-12-15 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), FLUAD TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5766 | click or scan EU-EC-10010972191 | | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Ventricular fibrillation (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, X-181), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), B/MASSACHUSETTS/2/2012-LIKE STRAIN (B/MASSACHUSETTS/2/2012, BX-51B)] (S - Influenza immunisation - Not applicable - [31d - n/a - Intramuscular]) |
| 5767 | click or scan EU-EC-10010971345 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5768 | click or scan EU-EC-10010971077 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5769 | click or scan EU-EC-10010971060 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5770 | click or scan EU-EC-10010970935 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Bedridden (2d - Recovered/Resolved - ), Coronary artery thrombosis (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - ), Fatigue (n/a - Recovered/Resolved - ), Gastrooesophageal reflux disease (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Influenza like illness (n/a - Recovered/Resolved - ), Loss of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - ), Myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5771 | click or scan EU-EC-10010970522 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5772 | click or scan EU-EC-10010970461 | | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5773 | click or scan EU-EC-10010970011 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Influenza like illness (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5774 | click or scan EU-EC-10010970007 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Hyperventilation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5775 | click or scan EU-EC-10010970005 |  | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 5776 | click or scan EU-EC-10010969974 |  | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Male | Brain injury (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5777 | click or scan EU-EC-10010969856 |  | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5778 | click or scan EU-EC-10010969588 |  | 2021-12-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Consciousness fluctuating (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Memory impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) |
| 5779 | click or scan EU-EC-10010969578 |  | 2021-12-15 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**), Foetal heart rate abnormal (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 5780 | click or scan EU-EC-10010969554 |  | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fibrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic steatosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial fibrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5781 | click or scan EU-EC-10010969477 |  | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (400min - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - ), Chest pain (n/a - Unknown - ), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Unknown - ), Dysstasia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Joint swelling (n/a - Unknown - ), Limb deformity (n/a - Unknown - ), Palpitations (n/a - Unknown - ), Pulmonary embolism (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Walking aid user (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5782 | click or scan EU-EC-10010969433 |  | 2021-12-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Encephalitis autoimmune (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - ), Hallucination (n/a - Unknown - ), Muscle rigidity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Slow speech (n/a - Recovering/Resolving - ), Sudden death (n/a - Fatal - **Results in Death**), Tremor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5783 | click or scan EU-EC-10010969425 | | 2021-12-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (3d - Unknown - ), Dizziness (3d - Unknown - ), Headache (3d - Unknown - ), Hypotension (3d - Fatal - **Results in Death**), Hypothermia (3d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Slow response to stimuli (3d - Unknown - ), Speech disorder (3d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5784 | click or scan EU-EC-10010969114 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5785 | click or scan EU-EC-10010968636 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Cough (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5786 | click or scan EU-EC-10010968392 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5787 | click or scan EU-EC-10010968340 | | 2021-12-15 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5788 | click or scan EU-EC-10010968334 | | 2021-12-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5789 | click or scan EU-EC-10010968128 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5790 | click or scan EU-EC-10010968108 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 5791 | click or scan EU-EC-10010968034 | | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5792 | click or scan EU-EC-10010967642 | | 2021-12-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5793 | click or scan EU-EC-10010966435 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain compression (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Carotid artery thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebellar tonsillar ectopia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Platybasia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superior sagittal sinus thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5794 | click or scan EU-EC-10010966182 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5795 | click or scan EU-EC-10010966119 | | 2021-12-15 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Haemorrhage urinary tract (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5796 | click or scan EU-EC-10010966012 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5797 | click or scan EU-EC-10010965794 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5798 | click or scan EU-EC-10010965738 | | 2021-12-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5799 | click or scan EU-EC-10010965292 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5800 | click or scan EU-EC-10010965154 | | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 5801 | click or scan EU-EC-10010965148 | | 2021-12-15 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 5802 | click or scan EU-EC-10010965016 | | 2021-12-15 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 5803 | click or scan EU-EC-10010964835 | | 2021-12-15 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5804 | click or scan EU-EC-10010964314 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5805 | click or scan EU-EC-10010963422 | | 2021-12-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chills (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Embolism (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Feeling of body temperature change (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5806 | click or scan EU-EC-10010963382 | | 2021-12-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pericarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5807 | click or scan EU-EC-10010963311 | | 2021-12-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - n/a]) |
| 5808 | click or scan EU-EC-10010963151 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site warmth (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5809 | click or scan EU-EC-10010962353 | | 2021-12-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **5810** | click or scan<br>EU-EC-10010962177 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| **5811** | click or scan<br>EU-EC-10010962090 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abscess drainage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Adenocarcinoma metastatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial natriuretic peptide normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Biopsy liver abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Biopsy lung abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood test abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bronchoscopy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Catheter placement (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chemotherapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Device leakage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drain placement (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ileus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunochemotherapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Incomplete course of vaccination (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung adenocarcinoma stage IV (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metastases to bone (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metastases to liver (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metastases to lymph nodes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericardial drainage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **5812** | click or scan<br>EU-EC-10010962068 | | 2021-12-15 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **5813** | click or scan<br>EU-EC-10010961988 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **5814** | click or scan<br>EU-EC-10010961945 | | 2021-12-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Epilepsy (n/a - Fatal - **Results in Death**), Glioblastoma (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Memory impairment (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5815 | click or scan EU-EC-10010961315 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Thirst (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5816 | click or scan EU-EC-10010961090 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5817 | click or scan EU-EC-10010960483 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5818 | click or scan EU-EC-10010960421 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5819 | click or scan EU-EC-10010960416 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5820 | click or scan EU-EC-10010960294 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haematuria (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal cancer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5821 | click or scan EU-EC-10010960292 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5822 | click or scan EU-EC-10010960169 | | 2021-12-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5823 | click or scan EU-EC-10010960160 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5824 | click or scan EU-EC-10010960158 | | 2021-12-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5825 | click or scan EU-EC-10010959897 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 5826 | click or scan EU-EC-10010959775 | | 2021-12-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Dementia (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5827 | click or scan EU-EC-10010959582 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5828 | click or scan EU-EC-10010959090 | | 2021-12-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5829 | click or scan EU-EC-10010958747 | | 2021-12-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5830 | click or scan EU-EC-10010958725 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5831 | click or scan EU-EC-10010958646 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diplegia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 5832 | click or scan EU-EC-10010958626 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Congenital Anomaly), Cough (n/a - Fatal - **Results in Death**, Congenital Anomaly), Decreased appetite (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5833 | click or scan EU-EC-10010958452 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5834 | click or scan EU-EC-10010958417 | | 2021-12-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5835 | click or scan EU-EC-10010958383 | | 2021-12-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Cough (n/a - Unknown - ), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5836 | click or scan EU-EC-10010958287 | | 2021-12-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5837 | click or scan EU-EC-10010957631 | | 2021-12-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 5838 | click or scan EU-EC-10010957569 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Male | Dehydration (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Hyperpyrexia (2d - Fatal - **Results in Death**), Hypertension (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5839 | click or scan EU-EC-10010957362 | | 2021-12-15 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 5840 | click or scan EU-EC-10010957356 | | 2021-12-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 5841 | click or scan EU-EC-10010957350 | | 2021-12-15 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5842 | click or scan EU-EC-10010956426 | | 2021-12-14 | Healthcare Professional | Non EEA | Not Specified | Female | Hepatic cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5843 | click or scan EU-EC-10010956080 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **5844** | click or scan EU-EC-10010955827 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Female | Intestinal ischaemia (10d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [B/BRISBANE/60/2008-LIKE VIRUS, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)-DERIVED STRAIN USED NYMC X-181, SORBITAN TRIOLEATE, POLYSORBATE 80, SODIUM CITRATE, A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/GUANDONG-MAONAN/SWL1536/2019 (H1N1)PDM09-LIKE VIRUS (A/VICTORIA/2454/2019 IVR-207), SQUALENE, CITRIC ACID, SORBITAN TRIOLEATE, POLYSORBATE 80, SODIUM CITRATE, CITRIC ACID ANHYDROUS, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/BRISBANE/9/2014 (WILD TYPE), SQUALENE, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181)] (S - Influenza immunisation - Not applicable - [1d - n/a - n/a]) |
| **5845** | click or scan EU-EC-10010955775 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Female | Decubitus ulcer (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic cyst (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune reconstitution inflammatory syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple sclerosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (274d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Prescribed underdose (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Progressive multifocal leukoencephalopathy (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination complication (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Unknown]), COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Unknown]), TYSABRI [NATALIZUMAB] (S - Relapsing-remitting multiple sclerosis - Not applicable - [n/a - 300mg - Unknown]), TYSABRI [NATALIZUMAB] (S - n/a - Not applicable - [n/a - 300mg - Unknown]) |
| **5846** | click or scan EU-EC-10010955231 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5847** | click or scan EU-EC-10010955145 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Hallucination (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5848** | click or scan EU-EC-10010955138 | | 2021-12-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5849** | click or scan EU-EC-10010955113 | | 2021-12-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ), Myalgia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5850 | click or scan EU-EC-10010954868 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5851 | click or scan EU-EC-10010954864 | | 2021-12-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Hepatic cancer (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5852 | click or scan EU-EC-10010954468 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 5853 | click or scan EU-EC-10010954413 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5854 | click or scan EU-EC-10010954350 | | 2021-12-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 5855 | click or scan EU-EC-10010954342 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5856 | click or scan EU-EC-10010954323 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - .5mL - n/a]) |
| 5857 | click or scan EU-EC-10010954310 | | 2021-12-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Incontinence (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5858 | click or scan EU-EC-10010954307 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 5859 | click or scan EU-EC-10010954302 | | 2021-12-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5860 | click or scan EU-EC-10010954297 | | 2021-12-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5861 | click or scan EU-EC-10010954295 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5862 | click or scan EU-EC-10010954292 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5863 | click or scan EU-EC-10010954055 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 5864 | click or scan EU-EC-10010954030 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5865 | click or scan EU-EC-10010954021 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5866 | click or scan EU-EC-10010954008 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5867 | click or scan EU-EC-10010953886 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5868 | click or scan EU-EC-10010953376 | | 2021-12-14 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5869 | click or scan EU-EC-10010953299 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haematoma (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), XARELTO [RIVAROXABAN] (S - Atrial fibrillation - Drug withdrawn - [n/a - n/a - Oral]) |
| 5870 | click or scan EU-EC-10010953258 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 2 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5871 | click or scan EU-EC-10010953227 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5872 | click or scan EU-EC-10010953226 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 5873 | click or scan EU-EC-10010953023 | | 2021-12-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Hypertension (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5874 | click or scan EU-EC-10010952794 | | 2021-12-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cough (46d - Fatal - **Results in Death**), Dementia (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Inappropriate schedule of product administration (n/a - Unknown - ), Influenza (n/a - Recovered/Resolved - ), Lower respiratory tract infection (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5875 | click or scan EU-EC-10010952793 | | 2021-12-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Foetal exposure during pregnancy (n/a - Unknown - ), Hydrocephalus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5876 | click or scan EU-EC-10010952754 | | 2021-12-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5877 | click or scan EU-EC-10010952370 | | 2021-12-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5878 | click or scan EU-EC-10010952359 | | 2021-12-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5879 | click or scan EU-EC-10010951978 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5880 | click or scan EU-EC-10010951939 | | 2021-12-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5881 | click or scan EU-EC-10010951923 | | 2021-12-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5882 | click or scan EU-EC-10010951918 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5883 | click or scan EU-EC-10010951707 | | 2021-12-14 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5884 | click or scan EU-EC-10010951534 | | 2021-12-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypertensive heart disease (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5885 | click or scan EU-EC-10010951382 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]) |
| 5886 | click or scan EU-EC-10010951356 | | 2021-12-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immobile (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5887 | click or scan EU-EC-10010951140 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Listless (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mastoiditis (n/a - Fatal - **Results in Death**), Meningoencephalitis bacterial (n/a - Fatal - **Results in Death**), Otitis media (n/a - Fatal - **Results in Death**), Pneumonia pneumococcal (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5888 | click or scan EU-EC-10010950874 | | 2021-12-14 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (20d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5889 | click or scan EU-EC-10010950638 | | 2021-12-14 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5890 | click or scan EU-EC-10010950591 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5891 | click or scan EU-EC-10010950494 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5892 | click or scan EU-EC-10010949923 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5893 | click or scan EU-EC-10010949865 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5894 | click or scan EU-EC-10010949446 | | 2021-12-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5895 | click or scan EU-EC-10010949421 | | 2021-12-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium increased (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture positive (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paralysis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory syncytial virus test positive (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcal infection (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcus test (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5896 | click or scan EU-EC-10010948751 | | 2021-12-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Alanine aminotransferase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anion gap (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aortic dilatation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood albumin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood alkaline phosphatase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bicarbonate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bilirubin normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood calcium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood chloride normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pH decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bundle branch block right (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Creatinine renal clearance increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram QRS complex abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gram stain positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell haemoglobin concentration decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5897 | click or scan EU-EC-10010948709 | | 2021-12-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysstasia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5898 | click or scan EU-EC-10010948619 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 5899 | click or scan EU-EC-10010948562 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asphyxia (n/a - Unknown - Life Threatening), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dysphagia (n/a - Unknown - ), Hypertension (n/a - Unknown - ), Rhinitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5900 | click or scan EU-EC-10010948319 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **5901** | click or scan EU-EC-10010947339 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Male | Somnolence (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .25mL - Intramuscular]), [FENTANYL] (S - Pain - n/a - [n/a - n/a - Transdermal]) |
| **5902** | click or scan EU-EC-10010947240 | | 2021-12-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **5903** | click or scan EU-EC-10010946967 | | 2021-12-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **5904** | click or scan EU-EC-10010946655 | | 2021-12-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **5905** | click or scan EU-EC-10010946630 | | 2021-12-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Parotitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **5906** | click or scan EU-EC-10010946534 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **5907** | click or scan EU-EC-10010946310 | | 2021-12-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **5908** | click or scan EU-EC-10010946279 | | 2021-12-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood culture positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Salmonellosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **5909** | click or scan EU-EC-10010946101 | | 2021-12-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5910 | click or scan EU-EC-10010945419 | | 2021-12-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 5911 | click or scan EU-EC-10010945354 | | 2021-12-14 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (46d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5912 | click or scan EU-EC-10010943349 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypocalcaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Low lung compliance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumomediastinum (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5913 | click or scan EU-EC-10010943166 | | 2021-12-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Immunisation (n/a - Fatal - **Results in Death**, Congenital Anomaly), Stillbirth (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5914 | click or scan EU-EC-10010942963 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure abnormal (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation abnormal (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5915 | click or scan EU-EC-10010942904 | | 2021-12-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 5916 | click or scan EU-EC-10010942879 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebellar haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5917 | click or scan EU-EC-10010942763 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ataxia (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - ), Sensory loss (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 5918 | click or scan EU-EC-10010942672 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angiogram cerebral abnormal (3d - Fatal - **Results in Death**), Brain oedema (3d - Fatal - **Results in Death**), Cerebral thrombosis (3d - Fatal - **Results in Death**), Cerebrovascular accident (3d - Fatal - **Results in Death**), Computerised tomogram head abnormal (3d - Fatal - **Results in Death**), Death (3d - Fatal - **Results in Death**), Hemiplegia (3d - Fatal - **Results in Death**), Laboratory test (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5919 | click or scan EU-EC-10010942392 |  | 2021-12-13 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening), Fluid intake reduced (n/a - Unknown - **Results in Death**, Life Threatening), General physical health deterioration (n/a - Unknown - **Results in Death**, Life Threatening), Hypophagia (n/a - Unknown - **Results in Death**, Life Threatening), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening), Productive cough (n/a - Unknown - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5920 | click or scan EU-EC-10010942332 |  | 2021-12-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 5921 | click or scan EU-EC-10010942324 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5922 | click or scan EU-EC-10010942078 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immediate post-injection reaction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxicologic test (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vision blurred (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5923 | click or scan EU-EC-10010941914 |  | 2021-12-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 5924 | click or scan EU-EC-10010941720 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5925 | click or scan EU-EC-10010941649 |  | 2021-12-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 5926 | click or scan EU-EC-10010941420 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5927 | click or scan EU-EC-10010941408 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5928 | click or scan EU-EC-10010941219 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5929 | click or scan EU-EC-10010941080 |  | 2021-12-13 | Non Healthcare Professional | EEA | Not Specified | Female | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 5930 | click or scan EU-EC-10010941047 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Arterial occlusive disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood pressure abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cholecystectomy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cholelithiasis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pancreatitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Surgery (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tracheostomy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5931 | click or scan EU-EC-10010940947 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| 5932 | click or scan EU-EC-10010940833 |  | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dizziness (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Septic shock (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5933 | click or scan EU-EC-10010940830 |  | 2021-12-13 | Non Healthcare Professional | EEA | Not Specified | Female | Acute kidney injury (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **5934** | click or scan EU-EC-10010940829 | | 2021-12-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5935** | click or scan EU-EC-10010940828 | | 2021-12-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dementia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5936** | click or scan EU-EC-10010940827 | | 2021-12-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5937** | click or scan EU-EC-10010940580 | | 2021-12-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5938** | click or scan EU-EC-10010940473 | | 2021-12-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Paraesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **5939** | click or scan EU-EC-10010940416 | | 2021-12-13 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - 1{DF} - Intramuscular]) |
| **5940** | click or scan EU-EC-10010940331 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **5941** | click or scan EU-EC-10010940321 | | 2021-12-13 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **5942** | click or scan EU-EC-10010940301 | | 2021-12-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5943 | click or scan EU-EC-10010940301 | | 2021-12-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| 5944 | click or scan EU-EC-10010940281 | | 2021-12-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 5945 | click or scan EU-EC-10010940279 | | 2021-12-13 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - .6mL - Intramuscular]) |
| 5946 | click or scan EU-EC-10010939947 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Life Threatening), Blood lactic acid (n/a - Fatal - **Results in Death**, Life Threatening), Chest X-ray (n/a - Fatal - **Results in Death**, Life Threatening), Computerised tomogram head (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening), Full blood count (n/a - Fatal - **Results in Death**, Life Threatening), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Life Threatening), Haemoptysis (n/a - Fatal - **Results in Death**, Life Threatening), Metabolic function test (n/a - Fatal - **Results in Death**, Life Threatening), Pain (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening), Urine analysis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 5947 | click or scan EU-EC-10010939569 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sluggishness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5948 | click or scan EU-EC-10010939241 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac monitoring (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardioversion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electroencephalogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound scan (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 5949 | click or scan EU-EC-10010938872 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Angina pectoris (0d - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Cardiac failure acute (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Myocardial ischaemia (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 5950 | click or scan EU-EC-10010938748 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Colitis ischaemic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5951 | click or scan EU-EC-10010938741 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5952 | click or scan EU-EC-10010938739 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5953 | click or scan EU-EC-10010938730 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood alkaline phosphatase increased (n/a - Unknown - ), Gastrooesophageal reflux disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stridor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5954 | click or scan EU-EC-10010938719 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Eczema herpeticum (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eye pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Herpes simplex encephalitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5955 | click or scan EU-EC-10010938694 | | 2021-12-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5956 | click or scan EU-EC-10010938693 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5957 | click or scan EU-EC-10010938679 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cachexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral atrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Unknown - ), Pallor (n/a - Unknown - ), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 5958 | click or scan EU-EC-10010938675 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5959 | click or scan EU-EC-10010938643 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Obesity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5960 | click or scan EU-EC-10010938639 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 5961 | click or scan EU-EC-10010938631 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 5962 | click or scan EU-EC-10010938432 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bronchoalveolar lavage abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemofiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pseudomonas infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sputum culture positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis in device (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5963 | click or scan EU-EC-10010938253 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysgeusia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Night sweats (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), T-cell lymphoma (161d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 5964 | click or scan EU-EC-10010938130 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood lactic acid increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral venous disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Scan with contrast abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5965 | click or scan EU-EC-10010938022 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5966 | click or scan EU-EC-10010938021 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Multisystem inflammatory syndrome in children (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5967 | click or scan EU-EC-10010937842 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Apnoea (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Lung neoplasm malignant (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Weight decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5968 | click or scan EU-EC-10010937828 | | 2021-12-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5969 | click or scan EU-EC-10010937808 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Apnoea (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Lung neoplasm malignant (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Weight decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5970 | click or scan EU-EC-10010937677 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Rhinitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 5971 | click or scan EU-EC-10010937660 | | 2021-12-13 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 5972 | click or scan EU-EC-10010937601 | | 2021-12-13 | Healthcare Professional | EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 5973 | click or scan EU-EC-10010937043 | | 2021-12-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulse absent (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5974 | click or scan EU-EC-10010936941 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Idiopathic pulmonary fibrosis (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5975 | click or scan EU-EC-10010936880 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Clostridium difficile infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5976 | click or scan EU-EC-10010936837 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intradermal]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5977 | click or scan EU-EC-10010936805 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood urea increased (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**), Haemodialysis (n/a - Fatal - **Results in Death**), Haemoglobin decreased (1d - Fatal - **Results in Death**), Hypervolaemia (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**), White blood cell count increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5978 | click or scan EU-EC-10010936707 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5979 | click or scan EU-EC-10010936637 |  | 2021-12-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (14d - Fatal - **Results in Death**), Chest X-ray abnormal (14d - Fatal - **Results in Death**), Cough (14d - Fatal - **Results in Death**), Death (14d - Fatal - **Results in Death**), Dyspnoea (14d - Fatal - **Results in Death**), Influenza virus test (n/a - Fatal - **Results in Death**), Pyrexia (14d - Fatal - **Results in Death**), Respiratory syncytial virus test (14d - Fatal - **Results in Death**), SARS-CoV-2 test positive (14d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5980 | click or scan EU-EC-10010936542 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), C-reactive protein increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 5981 | click or scan EU-EC-10010936500 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 5982 | click or scan EU-EC-10010936447 |  | 2021-12-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anxiety (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Impaired driving ability (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Moaning (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Respiratory tract congestion (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**), Walking aid user (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5983 | click or scan EU-EC-10010936430 |  | 2021-12-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood creatine phosphokinase MB (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatine phosphokinase normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Klebsiella infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia klebsiella (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin I (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine analysis abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 5984 | click or scan EU-EC-10010936423 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5985 | click or scan EU-EC-10010936367 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 5986 | click or scan EU-EC-10010936353 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 5987 | click or scan EU-EC-10010936294 |  | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5988 | click or scan EU-EC-10010936210 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5989 | click or scan EU-EC-10010936200 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5990 | click or scan EU-EC-10010936199 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 5991 | click or scan EU-EC-10010936176 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 5992 | click or scan EU-EC-10010936175 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 5993 | click or scan EU-EC-10010936172 |  | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **5994** | click or scan EU-EC-10010936171 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **5995** | click or scan EU-EC-10010936109 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), COVID-19 pneumonia (1d - Fatal - **Results in Death**), Cough (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **5996** | click or scan EU-EC-10010935964 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **5997** | click or scan EU-EC-10010935798 | | 2021-12-13 | Healthcare Professional | EEA | 18-64 Years | Male | Bronchitis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Capillary leak syndrome (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Colitis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised oedema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mass (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myositis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombophlebitis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thyroid mass (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Weight decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **5998** | click or scan EU-EC-10010935781 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Death (0d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Myalgia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **5999** | click or scan EU-EC-10010935753 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **6000** | click or scan EU-EC-10010935341 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6001 | click or scan EU-EC-10010935006 | | 2021-12-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 6002 | click or scan EU-EC-10010934995 | | 2021-12-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Eye movement disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 6003 | click or scan EU-EC-10010934888 | | 2021-12-13 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 6004 | click or scan EU-EC-10010934751 | | 2021-12-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6005 | click or scan EU-EC-10010934385 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6006 | click or scan EU-EC-10010934377 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock haemorrhagic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6007 | click or scan EU-EC-10010934263 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6008 | click or scan EU-EC-10010934083 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6009 | click or scan EU-EC-10010933908 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6010 | click or scan EU-EC-10010933816 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6011 | click or scan EU-EC-10010933587 | | 2021-12-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 6012 | click or scan EU-EC-10010933552 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood urine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6013 | click or scan EU-EC-10010933440 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6014 | click or scan EU-EC-10010933260 | | 2021-12-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6015 | click or scan EU-EC-10010933156 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cellulitis (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nephrotic syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0mo - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), [TOZINAMERAN] (S - n/a - Not applicable - [0mo - n/a - n/a]) |
| 6016 | click or scan EU-EC-10010933156 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cellulitis (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nephrotic syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0mo - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), [TOZINAMERAN] (S - n/a - Not applicable - [0mo - n/a - n/a]) |
| 6017 | click or scan EU-EC-10010933114 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6018 | click or scan EU-EC-10010932952 | | 2021-12-13 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6019 | click or scan EU-EC-10010932679 | | 2021-12-13 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital hydrocephalus (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly), Spina bifida (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 6020 | click or scan EU-EC-10010932517 | | 2021-12-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **6021** | click or scan EU-EC-10010932399 | | 2021-12-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Neck pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Osteomyelitis (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Spinal cord infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Spinal stroke (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| **6022** | click or scan EU-EC-10010932016 | | 2021-12-12 | Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary hypertension (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **6023** | click or scan EU-EC-10010931734 | | 2021-12-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6024** | click or scan EU-EC-10010931719 | | 2021-12-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (1d - Fatal - **Results in Death**), Condition aggravated (1d - Fatal - **Results in Death**), Diet refusal (1d - Fatal - **Results in Death**), Haemoglobin decreased (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6025** | click or scan EU-EC-10010931688 | | 2021-12-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (7d - Fatal - **Results in Death**), Cough (7d - Fatal - **Results in Death**), Death (7d - Fatal - **Results in Death**), Dyspnoea (7d - Fatal - **Results in Death**), Loss of consciousness (7d - Fatal - **Results in Death**), Resuscitation (7d - Fatal - **Results in Death**), SARS-CoV-2 test negative (7d - Fatal - **Results in Death**), Wheezing (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]), [INFLUENZA A VIRUS A/TEXAS/50/2012 X-223A (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA A VIRUS A/CALIFORNIA/7/2009 X-179A (H1N1) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA B VIRUS B/MASSACHUSETTS/2/2012 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA B VIRUS B/BRISBANE/60/2008 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6026** | click or scan EU-EC-10010931655 | | 2021-12-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6027** | click or scan EU-EC-10010931647 | | 2021-12-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **6028** | click or scan EU-EC-10010931635 |  | 2021-12-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anticoagulant therapy (29d - Fatal - **Results in Death**), COVID-19 (29d - Fatal - **Results in Death**), Echocardiogram abnormal (29d - Fatal - **Results in Death**), Ejection fraction normal (29d - Fatal - **Results in Death**), Embolism venous (29d - Fatal - **Results in Death**), Fibrin D dimer increased (29d - Fatal - **Results in Death**), Imaging procedure abnormal (29d - Fatal - **Results in Death**), Lung disorder (29d - Fatal - **Results in Death**), Pulmonary embolism (29d - Fatal - **Results in Death**), Pulmonary hypertension (29d - Fatal - **Results in Death**), Respiratory disorder (29d - Fatal - **Results in Death**), Right atrial dilatation (29d - Fatal - **Results in Death**), Ultrasound Doppler normal (29d - Fatal - **Results in Death**), Ventilation/perfusion scan abnormal (29d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6029** | click or scan EU-EC-10010931629 |  | 2021-12-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Lung infiltration (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Pneumoconiosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6030** | click or scan EU-EC-10010931617 |  | 2021-12-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6031** | click or scan EU-EC-10010931613 |  | 2021-12-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (48d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (48d - Fatal - **Results in Death**), COVID-19 pneumonia (48d - Fatal - **Results in Death**, Other Medically Important Condition), Death (48d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (48d - Fatal - **Results in Death**), Fall (48d - Fatal - **Results in Death**), Hypoxia (48d - Fatal - **Results in Death**, Other Medically Important Condition), Interstitial lung disease (48d - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (48d - Fatal - **Results in Death**), SARS-CoV-2 test positive (48d - Fatal - **Results in Death**), Subdural haematoma (48d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6032** | click or scan EU-EC-10010931612 |  | 2021-12-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6033** | click or scan EU-EC-10010931408 |  | 2021-12-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6034** | click or scan EU-EC-10010931264 |  | 2021-12-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6035** | click or scan EU-EC-10010931058 |  | 2021-12-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6036** | click or scan EU-EC-10010930906 |  | 2021-12-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Failure to thrive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6037 | click or scan EU-EC-10010930837 | | 2021-12-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6038 | click or scan EU-EC-10010930551 | | 2021-12-11 | Healthcare Professional | EEA | 65-85 Years | Male | Subarachnoid haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 6039 | click or scan EU-EC-10010930320 | | 2021-12-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Agitation (n/a - Fatal - **Results in Death**), Breath sounds abnormal (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**), Urine analysis normal (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6040 | click or scan EU-EC-10010929174 | | 2021-12-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Migraine (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6041 | click or scan EU-EC-10010929157 | | 2021-12-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6042 | click or scan EU-EC-10010929155 | | 2021-12-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6043 | click or scan EU-EC-10010928964 | | 2021-12-11 | Non Healthcare Professional | EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6044 | click or scan EU-EC-10010928781 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (3h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6045 | click or scan EU-EC-10010928405 | | 2021-12-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Blindness (n/a - Not Recovered/Not Resolved - **Results in Death**), Cerebral haemorrhage (3d - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Neck pain (n/a - Not Recovered/Not Resolved - **Results in Death**) | [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 6046 | click or scan EU-EC-10010928122 | | 2021-12-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |
| 6047 | click or scan EU-EC-10010928002 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6048 | click or scan EU-EC-10010927913 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6049 | click or scan EU-EC-10010927717 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6050 | click or scan EU-EC-10010927620 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Fatal - **Results in Death**), Restlessness (2d - Fatal - **Results in Death**), Tachycardia (2d - Fatal - **Results in Death**), Tachypnoea (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6051 | click or scan EU-EC-10010927585 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6052 | click or scan EU-EC-10010927570 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6053 | click or scan EU-EC-10010927452 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Life Threatening), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6054 | click or scan EU-EC-10010927439 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Metastases to liver (n/a - Unknown - Other Medically Important Condition), Pancreatic carcinoma (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 6055 | click or scan EU-EC-10010927433 | | 2021-12-10 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6056 | click or scan EU-EC-10010927389 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6057 | click or scan EU-EC-10010927387 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6058 | click or scan EU-EC-10010927109 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6059 | click or scan EU-EC-10010927051 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulse absent (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Syncope (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 6060 | click or scan EU-EC-10010926692 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 6061 | click or scan EU-EC-10010926277 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6062 | click or scan EU-EC-10010925816 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - ), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6063 | click or scan EU-EC-10010924134 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 6064 | click or scan EU-EC-10010924087 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6065 | click or scan EU-EC-10010924085 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 6066 | click or scan EU-EC-10010923949 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6067 | click or scan EU-EC-10010923919 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6068 | click or scan EU-EC-10010923916 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6069 | click or scan EU-EC-10010923899 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Angiogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6070 | click or scan EU-EC-10010923865 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (3d - Fatal - **Results in Death**, Other Medically Important Condition), Shunt thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6071 | click or scan EU-EC-10010923761 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Alanine aminotransferase (n/a - Fatal - **Results in Death**), Aspartate aminotransferase (n/a - Fatal - **Results in Death**), Bladder catheterisation (n/a - Fatal - **Results in Death**), Complication associated with device (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**), Full blood count (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), International normalised ratio (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6072 | click or scan EU-EC-10010923681 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Alveolar lung disease (n/a - Unknown - Other Medically Important Condition), Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastritis erosive (n/a - Unknown - Other Medically Important Condition), Hyperaemia (n/a - Unknown - ), Petechiae (n/a - Unknown - ), Pulmonary haemorrhage (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6073 | click or scan EU-EC-10010923655 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Activated partial thromboplastin time prolonged (n/a - Unknown - ), Alanine aminotransferase increased (n/a - Unknown - ), Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Aspartate aminotransferase increased (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - ), Basophil count increased (n/a - Unknown - ), Blood albumin decreased (n/a - Unknown - Other Medically Important Condition), Blood alkaline phosphatase increased (n/a - Unknown - ), Blood bilirubin increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin degradation products increased (n/a - Unknown - Other Medically Important Condition), Gamma-glutamyltransferase increased (n/a - Unknown - Other Medically Important Condition), Haematocrit decreased (n/a - Unknown - Other Medically Important Condition), Haemoglobin decreased (n/a - Unknown - Other Medically Important Condition), Interleukin level increased (n/a - Unknown - Other Medically Important Condition), Lymphocyte count decreased (n/a - Unknown - Other Medically Important Condition), Lymphoproliferative disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neutrophil count decreased (n/a - Unknown - Other Medically Important Condition), Pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Protein total decreased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Unknown - Other Medically Important Condition), White blood cell count decreased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6074 | click or scan EU-EC-10010923640 | | 2021-12-10 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal heart rate abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 6075 | click or scan EU-EC-10010923608 | | 2021-12-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Influenza like illness (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Unknown - ), Rhinitis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6076 | click or scan EU-EC-10010923595 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiplegia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6077 | click or scan EU-EC-10010923567 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6078 | click or scan EU-EC-10010923509 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6079 | click or scan EU-EC-10010923486 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Ejection fraction decreased (n/a - Fatal - **Results in Death**), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**), Infection (n/a - Fatal - **Results in Death**), Inflammation (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**), Left atrial enlargement (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Muscle atrophy (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Sinus tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6080 | click or scan EU-EC-10010923465 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6081 | click or scan EU-EC-10010923413 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (30min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6082 | click or scan EU-EC-10010923402 | | 2021-12-10 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 6083 | click or scan EU-EC-10010922884 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6084 | click or scan EU-EC-10010922734 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Male | Rectal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]) |
| 6085 | click or scan EU-EC-10010922620 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6086 | click or scan EU-EC-10010922380 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (3d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 6087 | click or scan EU-EC-10010922288 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 6088 | click or scan EU-EC-10010922277 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 6089 | click or scan EU-EC-10010922271 | | 2021-12-10 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 6090 | click or scan EU-EC-10010922230 | | 2021-12-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6091 | click or scan EU-EC-10010922140 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6092 | click or scan EU-EC-10010922093 | | 2021-12-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Heart rate increased (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6093 | click or scan EU-EC-10010922051 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6094 | click or scan EU-EC-10010921829 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6095 | click or scan EU-EC-10010921689 | | 2021-12-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | Lung infiltration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **6096** | click or scan EU-EC-10010921380 | | 2021-12-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **6097** | click or scan EU-EC-10010921190 | | 2021-12-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cold sweat (2h - Fatal - **Results in Death**), Shock (2h - Fatal - **Results in Death**), Somnolence (2h - Fatal - **Results in Death**), Tachycardia (2h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **6098** | click or scan EU-EC-10010921001 | | 2021-12-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6099** | click or scan EU-EC-10010920997 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6100** | click or scan EU-EC-10010920996 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **6101** | click or scan EU-EC-10010920954 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Breath sounds abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid pulse abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Extubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart sounds abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pupillary light reflex tests abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Restlessness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **6102** | click or scan EU-EC-10010920316 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| **6103** | click or scan EU-EC-10010919603 | | 2021-12-10 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral infarction (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **6104** | click or scan EU-EC-10010919461 | | 2021-12-10 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6105 | click or scan EU-EC-10010918912 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]), [LEUPRORELIN, LEUPRORELIN ACETATE] (S - Prostate cancer - Unknown - [n/a - 23mg - Subcutaneous]) |
| 6106 | click or scan EU-EC-10010918355 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6107 | click or scan EU-EC-10010918354 | | 2021-12-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), [BUDESONIDE] (I - n/a - n/a - [n/a - n/a - n/a]), [DEXCHLORPHENIRAMINE MALEATE, BETAMETHASONE] (I - n/a - n/a - [n/a - n/a - n/a]), [FEXOFENADINE HYDROCHLORIDE] (I - n/a - n/a - [n/a - n/a - n/a]) |
| 6108 | click or scan EU-EC-10010918194 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6109 | click or scan EU-EC-10010918184 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Cardiac disorder (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6110 | click or scan EU-EC-10010918176 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coronary artery stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6111 | click or scan EU-EC-10010918166 | | 2021-12-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6112 | click or scan EU-EC-10010918165 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6113 | click or scan EU-EC-10010918130 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6114 | click or scan EU-EC-10010918028 |  | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oliguria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine analysis abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6115 | click or scan EU-EC-10010917872 |  | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6116 | click or scan EU-EC-10010917624 |  | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6117 | click or scan EU-EC-10010917603 |  | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6118 | click or scan EU-EC-10010917435 |  | 2021-12-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6119 | click or scan EU-EC-10010917026 |  | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardioversion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**), Full blood count (n/a - Fatal - **Results in Death**), Intraosseous access placement (n/a - Fatal - **Results in Death**), Metabolic function test (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Troponin (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6120 | click or scan EU-EC-10010916759 |  | 2021-12-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abnormal loss of weight (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebrovascular accident (2d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6121 | click or scan EU-EC-10010916616 |  | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6122 | click or scan EU-EC-10010916569 |  | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6123 | click or scan EU-EC-10010916462 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 6124 | click or scan EU-EC-10010916436 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6125 | click or scan EU-EC-10010916003 | | 2021-12-10 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 6126 | click or scan EU-EC-10010916003 | | 2021-12-10 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 6127 | click or scan EU-EC-10010915866 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 6128 | click or scan EU-EC-10010915834 | | 2021-12-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6129 | click or scan EU-EC-10010915801 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6130 | click or scan EU-EC-10010915724 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Magnetic resonance imaging abnormal (n/a - Fatal - **Results in Death**), Mechanical ventilation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6131 | click or scan EU-EC-10010915717 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pain (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6132 | click or scan<br>EU-EC-10010915610 |  | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Alanine aminotransferase increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Back pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Bacterial test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Bicytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Biopsy bone marrow (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Biopsy skin normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blood bilirubin increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blood creatinine increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blood culture negative (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blood immunoglobulin G (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blood test normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Bronchoalveolar lavage normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Bronchoscopy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), CSF glucose increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), CSF lymphocyte count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), CSF protein normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), CSF white blood cell count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Chest X-ray normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Clostridium test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Computerised tomogram head normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Computerised tomogram normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Computerised tomogram spine (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cryoglobulinaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cryoglobulins present (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6133 | click or scan<br>EU-EC-10010915565 |  | 2021-12-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | Hypersensitivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6134 | click or scan<br>EU-EC-10010915555 |  | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6135 | click or scan<br>EU-EC-10010915500 |  | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**), Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Hemiparesis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hepatic cirrhosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hepatorenal syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intensive care (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6136 | click or scan EU-EC-10010915426 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6137 | click or scan EU-EC-10010915422 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6138 | click or scan EU-EC-10010915092 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6139 | click or scan EU-EC-10010914956 | | 2021-12-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Embolism (n/a - Fatal - **Results in Death**), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6140 | click or scan EU-EC-10010914876 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6141 | click or scan EU-EC-10010914873 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease aggravated (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6142 | click or scan EU-EC-10010914871 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6143 | click or scan EU-EC-10010914792 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | LONSURF [TRIFLURIDINE, TIPIRACIL] (S - Colorectal cancer metastatic - Unknown - [n/a - n/a - Oral]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6144 | click or scan EU-EC-10010914791 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal abscess (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6145 | click or scan EU-EC-10010914790 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Exposure during pregnancy (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6146 | click or scan EU-EC-10010914785 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6147 | click or scan EU-EC-10010914671 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6148 | click or scan EU-EC-10010914593 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6149 | click or scan EU-EC-10010914586 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gastric cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]) |
| 6150 | click or scan EU-EC-10010914561 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cyanosis (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Haematemesis (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Peripheral coldness (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6151 | click or scan EU-EC-10010914490 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6152 | click or scan EU-EC-10010914257 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6153 | click or scan EU-EC-10010914222 | | 2021-12-10 | Healthcare Professional | EEA | 65-85 Years | Male | Autoimmune disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6154 | click or scan EU-EC-10010914021 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6155 | click or scan EU-EC-10010914011 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6156 | click or scan EU-EC-10010913489 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6157 | click or scan EU-EC-10010913438 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6158 | click or scan EU-EC-10010913416 | | 2021-12-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6159 | click or scan EU-EC-10010913398 | | 2021-12-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Disorientation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6160 | click or scan EU-EC-10010913373 | | 2021-12-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6161 | click or scan EU-EC-10010913043 | | 2021-12-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (196d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 6162 | click or scan EU-EC-10010911522 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6163 | click or scan EU-EC-10010911350 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6164 | click or scan EU-EC-10010911261 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ataxia (n/a - Fatal - **Results in Death**), Encephalitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 6165 | click or scan EU-EC-10010911105 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory acidosis (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6166 | click or scan EU-EC-10010911081 | | 2021-12-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Autoimmune encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hallucination (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hip fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myoclonus (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| 6167 | click or scan EU-EC-10010911011 | | 2021-12-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6168 | click or scan EU-EC-10010910740 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6169 | click or scan EU-EC-10010910738 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | 5q minus syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6170 | click or scan EU-EC-10010910735 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6171 | click or scan EU-EC-10010910534 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6172 | click or scan EU-EC-10010910498 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6173 | click or scan EU-EC-10010910423 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6174 | click or scan EU-EC-10010910369 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6175 | click or scan EU-EC-10010910257 | | 2021-12-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrioventricular block complete (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6176 | click or scan EU-EC-10010910211 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6177 | click or scan EU-EC-10010910157 | | 2021-12-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Peripheral artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6178 | click or scan EU-EC-10010910047 | | 2021-12-09 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6179 | click or scan EU-EC-10010909517 | | 2021-12-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6180 | click or scan EU-EC-10010909477 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (16d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Diabetes mellitus inadequate control (16d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Malaise (16d - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6181 | click or scan EU-EC-10010909435 | | 2021-12-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6182 | click or scan EU-EC-10010909222 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6183 | click or scan EU-EC-10010909182 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6184 | click or scan EU-EC-10010908818 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6185 | click or scan EU-EC-10010908701 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6186 | click or scan EU-EC-10010908324 |  | 2021-12-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Breast pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Unknown - ), Gait inability (n/a - Unknown - ), Loss of personal independence in daily activities (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Paraplegia (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary mass (n/a - Unknown - ), Sensory loss (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Spinal fracture (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6187 | click or scan EU-EC-10010908320 |  | 2021-12-09 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Not Recovered/Not Resolved - ), Back pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6188 | click or scan EU-EC-10010908262 |  | 2021-12-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6189 | click or scan EU-EC-10010907949 |  | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6190 | click or scan EU-EC-10010907753 |  | 2021-12-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Liver disorder (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6191 | click or scan EU-EC-10010907733 |  | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pain (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6192 | click or scan EU-EC-10010907579 |  | 2021-12-09 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 6193 | click or scan EU-EC-10010907570 |  | 2021-12-09 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6194 | click or scan EU-EC-10010907561 |  | 2021-12-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Immune-mediated myositis (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**), Sjogren's syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (S - Atrial fibrillation - Dose not changed - [402d - 1 {DF} - Oral - More in ICSR]) |
| 6195 | click or scan EU-EC-10010906991 |  | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hiccups (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6196 | click or scan EU-EC-10010906902 |  | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6197 | click or scan EU-EC-10010906894 |  | 2021-12-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - ), Phlebitis (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6198 | click or scan EU-EC-10010906863 |  | 2021-12-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6199 | click or scan EU-EC-10010906862 |  | 2021-12-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6200 | click or scan EU-EC-10010906858 |  | 2021-12-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (103d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6201 | click or scan EU-EC-10010906844 |  | 2021-12-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Hot flush (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6202 | click or scan EU-EC-10010906838 |  | 2021-12-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Tachycardia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6203 | click or scan EU-EC-10010906738 |  | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Petechiae (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6204 | click or scan EU-EC-10010906700 |  | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6205 | click or scan EU-EC-10010906406 |  | 2021-12-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6206 | click or scan EU-EC-10010906402 | | 2021-12-09 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 immunisation (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6207 | click or scan EU-EC-10010905968 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6208 | click or scan EU-EC-10010905726 | | 2021-12-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure congestive (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 6209 | click or scan EU-EC-10010905710 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Muscle rigidity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 6210 | click or scan EU-EC-10010905680 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6211 | click or scan EU-EC-10010905655 | | 2021-12-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6212 | click or scan EU-EC-10010905005 | | 2021-12-09 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiovascular disorder (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6213 | click or scan EU-EC-10010904271 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (n/a - Unknown - Life Threatening), Circulatory collapse (n/a - Not Recovered/Not Resolved - Life Threatening), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening), Feeling hot (n/a - Not Recovered/Not Resolved - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Pulmonary embolism (5d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 6214 | click or scan EU-EC-10010904220 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6215 | click or scan EU-EC-10010904218 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6216 | click or scan EU-EC-10010903942 | | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6217 | click or scan EU-EC-10010902675 |  | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure systolic increased (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6218 | click or scan EU-EC-10010902650 |  | 2021-12-09 | Non Healthcare Professional | EEA | Not Specified | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6219 | click or scan EU-EC-10010902550 |  | 2021-12-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6220 | click or scan EU-EC-10010902456 |  | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 6221 | click or scan EU-EC-10010902430 |  | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6222 | click or scan EU-EC-10010902331 |  | 2021-12-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 6223 | click or scan EU-EC-10010902202 |  | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6224 | click or scan EU-EC-10010902052 |  | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6225 | click or scan EU-EC-10010901762 |  | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 6226 | click or scan EU-EC-10010900779 |  | 2021-12-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Foetal death (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6227 | click or scan EU-EC-10010900674 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Immunisation (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6228 | click or scan EU-EC-10010899706 | | 2021-12-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (5241min - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperuricaemia (n/a - Unknown - ), Rectal haemorrhage (15d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]), ELIQUIS [APIXABAN] (S - Cerebrovascular accident prophylaxis - Dose reduced - [n/a - 2.5mg - Oral - More in ICSR]) |
| 6229 | click or scan EU-EC-10010899488 | | 2021-12-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 6230 | click or scan EU-EC-10010898693 | | 2021-12-08 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 6231 | click or scan EU-EC-10010897939 | | 2021-12-08 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6232 | click or scan EU-EC-10010897923 | | 2021-12-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6233 | click or scan EU-EC-10010897809 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6234 | click or scan EU-EC-10010897714 | | 2021-12-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6235 | click or scan EU-EC-10010896976 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Male | Urosepsis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6236 | click or scan EU-EC-10010896773 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6237 | click or scan EU-EC-10010896684 | | 2021-12-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6238 | click or scan EU-EC-10010896292 | | 2021-12-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6239 | click or scan EU-EC-10010896277 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| 6240 | click or scan EU-EC-10010896260 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Male | Shock (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 6241 | click or scan EU-EC-10010896249 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| 6242 | click or scan EU-EC-10010896183 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6243 | click or scan EU-EC-10010896100 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | CELLCEPT 250 MG CAPSULES [MYCOPHENOLATE MOFETIL] (S - Prophylaxis against transplant rejection - Dose not changed - [n/a - n/a - Oral]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [PREDNISONE] (S - Prophylaxis against transplant rejection - Dose not changed - [n/a - 5mg - Oral]), [TACROLIMUS, TACROLIMUS MONOHYDRATE] (S - Prophylaxis against transplant rejection - Dose not changed - [n/a - 4mg - Oral]) |
| 6244 | click or scan EU-EC-10010896077 | | 2021-12-08 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6245 | click or scan EU-EC-10010895593 | | 2021-12-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6246 | click or scan EU-EC-10010895069 | | 2021-12-08 | Healthcare Professional | EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6247 | click or scan EU-EC-10010894912 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6248 | click or scan EU-EC-10010894897 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6249 | click or scan EU-EC-10010894385 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - ), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6250 | click or scan EU-EC-10010894362 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6251 | click or scan EU-EC-10010894359 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Oropharyngeal discomfort (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6252 | click or scan EU-EC-10010894358 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**, Life Threatening), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Haemothorax (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [3min - n/a - Intramuscular]) |
| 6253 | click or scan EU-EC-10010894354 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Basal ganglia haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain compression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Glossoptosis (n/a - Unknown - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory depression (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6254 | click or scan EU-EC-10010894333 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 6255 | click or scan EU-EC-10010894315 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Recovered/Resolved - ), Insomnia (n/a - Recovered/Resolved - ), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6256 | click or scan EU-EC-10010894300 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6257 | click or scan EU-EC-10010894299 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Recovered/Resolved - Other Medically Important Condition), Cerebral ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Stress cardiomyopathy (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6258 | click or scan EU-EC-10010894144 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest discomfort (n/a - Unknown - ), Cold sweat (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Shock (n/a - Unknown - Other Medically Important Condition), Viral myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), DARATUMUMAB [DARATUMUMAB] (S - Plasma cell myeloma - Not applicable - [15d - n/a - Subcutaneous]), REVLIMID [LENALIDOMIDE] (S - Plasma cell myeloma - Not applicable - [19d - n/a - Oral]) |
| 6259 | click or scan EU-EC-10010894140 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Muscle rigidity (n/a - Unknown - Other Medically Important Condition), Pyelonephritis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6260 | click or scan EU-EC-10010894080 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Discomfort (n/a - Unknown - ), Fall (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Incontinence (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6261 | click or scan EU-EC-10010893888 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (21d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Calculus bladder (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Palliative care (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tachypnoea (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6262 | click or scan EU-EC-10010893824 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Oropharyngeal discomfort (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pharyngitis (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6263 | click or scan EU-EC-10010893593 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL BP] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 6264 | click or scan EU-EC-10010893436 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6265 | click or scan EU-EC-10010893211 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6266 | click or scan EU-EC-10010893185 | | 2021-12-08 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6267 | click or scan EU-EC-10010893071 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 6268 | click or scan EU-EC-10010892936 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - ), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6269 | click or scan EU-EC-10010892747 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myalgia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 6270 | click or scan EU-EC-10010892742 | | 2021-12-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6271 | click or scan EU-EC-10010891712 | | 2021-12-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6272 | click or scan EU-EC-10010891558 | | 2021-12-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 6273 | click or scan EU-EC-10010891474 | | 2021-12-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Hypotonia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6274 | click or scan EU-EC-10010891224 | | 2021-12-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Gastritis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6275 | click or scan EU-EC-10010891215 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypertrophic cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6276 | click or scan EU-EC-10010891154 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Delusion (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Delusion (n/a - Unknown - Life Threatening, Other Medically Important Condition), Mood altered (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Suicidal behaviour (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Suicidal ideation (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Thinking abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| 6277 | click or scan EU-EC-10010891073 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6278 | click or scan EU-EC-10010890863 | | 2021-12-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (45min - Fatal - **Results in Death**), Myocardial infarction (45min - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1 d - .5 mL - Intramuscular]) |
| 6279 | click or scan EU-EC-10010889989 | | 2021-12-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Organ failure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Skin reaction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 6280 | click or scan EU-EC-10010889644 | | 2021-12-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6281 | click or scan EU-EC-10010889487 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disease progression (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6282 | click or scan EU-EC-10010889428 | | 2021-12-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6283 | click or scan EU-EC-10010889414 | | 2021-12-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1 d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6284 | click or scan EU-EC-10010889397 | | 2021-12-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6285 | click or scan EU-EC-10010889245 | | 2021-12-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (1 d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6286 | click or scan EU-EC-10010888409 | | 2021-12-08 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6287 | click or scan EU-EC-10010888118 | | 2021-12-08 | Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 6288 | click or scan EU-EC-10010887587 | | 2021-12-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6289 | click or scan EU-EC-10010887509 | | 2021-12-08 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Hyperpyrexia (0d - Fatal - **Results in Death**), Tremor (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6290 | click or scan EU-EC-10010885310 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6291 | click or scan EU-EC-10010884959 | | 2021-12-07 | Healthcare Professional | Non EEA | Not Specified | Female | Influenza like illness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6292 | click or scan EU-EC-10010884889 | | 2021-12-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6293 | click or scan EU-EC-10010884882 | | 2021-12-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6294 | click or scan EU-EC-10010884881 | | 2021-12-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Tachycardia (19d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6295 | click or scan EU-EC-10010884863 | | 2021-12-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6296 | click or scan EU-EC-10010884850 | | 2021-12-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **6297** | click or scan EU-EC-10010884744 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6298** | click or scan EU-EC-10010884636 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6299** | click or scan EU-EC-10010884618 | | 2021-12-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Tachycardia (39d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **6300** | click or scan EU-EC-10010884607 | | 2021-12-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Bedridden (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **6301** | click or scan EU-EC-10010884604 | | 2021-12-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **6302** | click or scan EU-EC-10010884250 | | 2021-12-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Intestinal infarction (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **6303** | click or scan EU-EC-10010884213 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6304** | click or scan EU-EC-10010884204 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Alveolar proteinosis (n/a - Fatal - **Results in Death**), Emphysema (n/a - Fatal - **Results in Death**), Glomerulonephritis proliferative (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **6305** | click or scan EU-EC-10010883904 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6306** | click or scan EU-EC-10010883009 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pallor (n/a - Fatal - **Results in Death**), Protrusion tongue (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **6307** | click or scan EU-EC-10010882793 | | 2021-12-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6308** | click or scan EU-EC-10010882693 | | 2021-12-07 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6309** | click or scan EU-EC-10010882625 | | 2021-12-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **6310** | click or scan EU-EC-10010882359 | | 2021-12-07 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Trisomy 21 (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| **6311** | click or scan EU-EC-10010882178 | | 2021-12-07 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6312** | click or scan EU-EC-10010882174 | | 2021-12-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **6313** | click or scan EU-EC-10010882092 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **6314** | click or scan EU-EC-10010881721 | | 2021-12-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **6315** | click or scan EU-EC-10010881341 | | 2021-12-07 | Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **6316** | click or scan EU-EC-10010881244 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6317 | click or scan EU-EC-10010881179 | | 2021-12-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 6318 | click or scan EU-EC-10010881094 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 6319 | click or scan EU-EC-10010880836 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malignant pleural effusion (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumothorax (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Stress cardiomyopathy (n/a - Unknown - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [ABEMACICLIB] (S - Breast cancer recurrent, Invasive ductal breast carcinoma - Drug withdrawn - [21d - 200mg - Oral - More in ICSR]), [ANASTROZOLE] (S - Breast cancer recurrent, Invasive ductal breast carcinoma - Drug withdrawn - [42d - 1mg - Oral - More in ICSR]) |
| 6320 | click or scan EU-EC-10010880788 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sputum discoloured (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Walking disability (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6321 | click or scan EU-EC-10010880138 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6322 | click or scan EU-EC-10010879897 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Metabolic acidosis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 6323 | click or scan EU-EC-10010879461 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6324 | click or scan EU-EC-10010879377 | | 2021-12-07 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 6325 | click or scan EU-EC-10010879376 | | 2021-12-07 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6326 | click or scan EU-EC-10010879355 | | 2021-12-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6327 | click or scan EU-EC-10010879226 | | 2021-12-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 6328 | click or scan EU-EC-10010879193 | | 2021-12-07 | Healthcare Professional | EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 6329 | click or scan EU-EC-10010879126 | | 2021-12-07 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6330 | click or scan EU-EC-10010878804 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Asthma (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6331 | click or scan EU-EC-10010878653 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6332 | click or scan EU-EC-10010878432 | | 2021-12-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Brain stem stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6333 | click or scan EU-EC-10010878365 | | 2021-12-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6334 | click or scan EU-EC-10010877812 | | 2021-12-07 | Healthcare Professional | EEA | 18-64 Years | Female | Headache (n/a - Unknown - Other Medically Important Condition), Pre-eclampsia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6335 | click or scan EU-EC-10010877742 | | 2021-12-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (8d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6336 | click or scan EU-EC-10010877520 | | 2021-12-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6337 | click or scan EU-EC-10010877252 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral ventricular rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - ), Hypertensive emergency (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6338 | click or scan EU-EC-10010877211 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6339 | click or scan EU-EC-10010877175 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bone pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Gingival swelling (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 6340 | click or scan EU-EC-10010876520 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1min - 1{DF} - Intramuscular]) |
| 6341 | click or scan EU-EC-10010876185 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Angioedema (6d - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Angioedema (n/a - Unknown - Life Threatening, Other Medically Important Condition), Gout (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Life Threatening, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Life Threatening), Lower respiratory tract infection (n/a - Unknown - Life Threatening, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pruritus (n/a - Unknown - Life Threatening, Other Medically Important Condition), Swollen tongue (n/a - Unknown - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [ALLOPURINOL] (S - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [CEFALEXIN, CEFALEXIN MONOHYDRATE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 6342 | click or scan EU-EC-10010875978 | | 2021-12-07 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 6343 | click or scan EU-EC-10010875924 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 6344 | click or scan EU-EC-10010875849 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - ), Overdose (n/a - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6345 | click or scan EU-EC-10010875749 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - ), Radiotherapy (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 6346 | click or scan EU-EC-10010875691 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood test (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - Unknown]) |
| 6347 | click or scan EU-EC-10010875617 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6348 | click or scan EU-EC-10010875300 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6349 | click or scan EU-EC-10010875207 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6350 | click or scan EU-EC-10010875181 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Disabling), Paralysis (46d - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 6351 | click or scan EU-EC-10010875148 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 6352 | click or scan EU-EC-10010875061 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Unknown - Life Threatening), Chronic kidney disease (n/a - Not Recovered/Not Resolved - Life Threatening), Death (1d - Fatal - **Results in Death**, Life Threatening), Urinary incontinence (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6353 | click or scan EU-EC-10010875056 | | 2021-12-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6354 | click or scan EU-EC-10010875051 | | 2021-12-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6355 | click or scan EU-EC-10010874848 | | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Amnesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Anger (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Aortic stenosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Delusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Dementia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Hyperventilation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Peripheral swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6356 | click or scan EU-EC-10010874735 | | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agonal respiration (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6357 | click or scan EU-EC-10010874716 |  | 2021-12-07 | Healthcare Professional | Non EEA | Not Specified | Male | Chest discomfort (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6358 | click or scan EU-EC-10010874713 |  | 2021-12-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Unknown - Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (8d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6359 | click or scan EU-EC-10010873610 |  | 2021-12-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle tightness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Ventricular hypertrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6360 | click or scan EU-EC-10010872618 |  | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (8d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1mL - Intramuscular]) |
| 6361 | click or scan EU-EC-10010872394 |  | 2021-12-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1min - 1{DF} - Intramuscular]) |
| 6362 | click or scan EU-EC-10010872284 |  | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6363 | click or scan EU-EC-10010872129 |  | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6364 | click or scan EU-EC-10010872007 |  | 2021-12-06 | Healthcare Professional | EEA | 65-85 Years | Male | Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6365 | click or scan EU-EC-10010871719 |  | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6366 | click or scan EU-EC-10010871560 |  | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6367 | click or scan EU-EC-10010871549 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6368 | click or scan EU-EC-10010871434 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Electrical burn (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6369 | click or scan EU-EC-10010871433 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6370 | click or scan EU-EC-10010871429 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6371 | click or scan EU-EC-10010871235 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6372 | click or scan EU-EC-10010871099 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6373 | click or scan EU-EC-10010870957 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6374 | click or scan EU-EC-10010870796 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6375 | click or scan EU-EC-10010870672 | | 2021-12-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6376 | click or scan EU-EC-10010870479 | | 2021-12-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 6377 | click or scan EU-EC-10010870209 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6378 | click or scan EU-EC-10010870190 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Neoplasm malignant (n/a - Fatal - **Results in Death**), Oesophageal varices haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 6379 | click or scan EU-EC-10010869974 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain herniation (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (5d - Fatal - **Results in Death**, Other Medically Important Condition), Encephalopathy (3d - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic function abnormal (n/a - Unknown - ), Injection site reaction (n/a - Unknown - ), Renal impairment (n/a - Unknown - Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (5d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 6380 | click or scan EU-EC-10010869223 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6381 | click or scan EU-EC-10010868931 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6382 | click or scan EU-EC-10010868707 | | 2021-12-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic dilatation (n/a - Fatal - **Results in Death**), Cardiac disorder (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Dysphonia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Muscle contractions involuntary (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6383 | click or scan EU-EC-10010868706 | | 2021-12-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6384 | click or scan EU-EC-10010868593 | | 2021-12-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 6385 | click or scan EU-EC-10010868379 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6386 | click or scan EU-EC-10010868282 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Anaemia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6387 | click or scan EU-EC-10010867996 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Cold sweat (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6388 | click or scan EU-EC-10010867983 | | 2021-12-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Labile hypertension (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6389 | click or scan EU-EC-10010867979 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Alcohol poisoning (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening), Condition aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening), General physical health deterioration (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperventilation (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6390 | click or scan EU-EC-10010867972 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6391 | click or scan EU-EC-10010867868 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6392 | click or scan EU-EC-10010867865 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6393 | click or scan EU-EC-10010867838 | | 2021-12-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6394 | click or scan EU-EC-10010867761 | | 2021-12-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 6395 | click or scan EU-EC-10010867699 | | 2021-12-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6396 | click or scan EU-EC-10010867502 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6397 | click or scan EU-EC-10010867325 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6398 | click or scan EU-EC-10010867214 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6399 | click or scan EU-EC-10010866926 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6400 | click or scan EU-EC-10010866925 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haematochezia (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6401 | click or scan EU-EC-10010866679 | | 2021-12-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6402 | click or scan EU-EC-10010866559 | | 2021-12-06 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6403 | click or scan EU-EC-10010866526 | | 2021-12-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6404 | click or scan EU-EC-10010866522 | | 2021-12-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6405 | click or scan EU-EC-10010866508 | | 2021-12-06 | Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 6406 | click or scan EU-EC-10010866447 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pain in extremity (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6407 | click or scan EU-EC-10010866416 | | 2021-12-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6408 | click or scan EU-EC-10010866410 | | 2021-12-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Migraine (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6409 | click or scan EU-EC-10010866408 | | 2021-12-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6410 | click or scan EU-EC-10010866406 | | 2021-12-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6411 | click or scan EU-EC-10010866403 | | 2021-12-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6412 | click or scan EU-EC-10010866304 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Contusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (0mo - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6413 | click or scan EU-EC-10010866212 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6414 | click or scan EU-EC-10010865792 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6415 | click or scan EU-EC-10010865368 | | 2021-12-06 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6416 | click or scan EU-EC-10010865293 | | 2021-12-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), General physical condition abnormal (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6417 | click or scan EU-EC-10010864603 | | 2021-12-06 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (0d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling of despair (0d - Fatal - **Results in Death**, Other Medically Important Condition), Mydriasis (0d - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (0d - Fatal - **Results in Death**, Other Medically Important Condition) | JANSSEN COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 6418 | click or scan EU-EC-10010864184 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Antisynthetase syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diffuse alveolar damage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6419 | click or scan EU-EC-10010864168 | | 2021-12-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6420 | click or scan EU-EC-10010864142 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Small cell lung cancer (n/a - Unknown - Other Medically Important Condition), Trismus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6421 | click or scan EU-EC-10010863396 | | 2021-12-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6422 | click or scan EU-EC-10010863367 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6423 | click or scan EU-EC-10010863361 | | 2021-12-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6424 | click or scan EU-EC-10010862786 | | 2021-12-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6425 | click or scan EU-EC-10010862784 | | 2021-12-06 | Non Healthcare Professional | Non EEA | Not Specified | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple sclerosis (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6426 | click or scan EU-EC-10010862751 | | 2021-12-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Acute coronary syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cold sweat (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin I increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6427 | click or scan EU-EC-10010861406 | | 2021-12-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 6428 | click or scan EU-EC-10010860330 | | 2021-12-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Influenza like illness (7d - Fatal - **Results in Death**, Life Threatening), SARS-CoV-2 antibody test (7d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 6429 | click or scan EU-EC-10010858723 | | 2021-12-05 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6430 | click or scan EU-EC-10010853147 | | 2021-12-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 6431 | click or scan EU-EC-10010853077 | | 2021-12-04 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), FLUAD TETRA [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6432 | click or scan EU-EC-10010852709 | | 2021-12-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhage (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6433 | click or scan EU-EC-10010851442 | | 2021-12-03 | Healthcare Professional | EEA | 65-85 Years | Male | Systemic inflammatory response syndrome (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), [B/BRISBANE/60/2008-LIKE VIRUS, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)-DERIVED STRAIN USED NYMC X-181, SORBITAN TRIOLEATE, POLYSORBATE 80, SODIUM CITRATE, A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/GUANDONG-MAONAN/SWL1536/2019 (H1N1)PDM09-LIKE VIRUS (A/VICTORIA/2454/2019 IVR-207), SQUALENE, CITRIC ACID, SORBITAN TRIOLEATE, POLYSORBATE 80, SODIUM CITRATE, CITRIC ACID ANHYDROUS, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/BRISBANE/9/2014 (WILD TYPE), SQUALENE, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181)] (S - Influenza immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 6434 | click or scan EU-EC-10010851306 | | 2021-12-03 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperhidrosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]), FLUAD TETRA SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE [B/PHUKET/3073/2013-LIKE STRAIN (B/PHUKET/3073/2013, BVR-1B), B/WASHINGTON/02/2019-LIKE VIRUS (B/VICTORIA/705/2018 BVR-11), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), A/CAMBODIA/E0826360/2020 (H3N2)-LIKE STRAIN (A/CAMBODIA/E0826360/2020 IVR-224), MF59C.1] (S - Immunisation - Not applicable - [1d - 1{DF} - Unknown]) |
| 6435 | click or scan EU-EC-10010850437 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Unknown - Other Medically Important Condition), Bundle branch block right (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fibrin D dimer increased (11d - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Troponin (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Troponin I increased (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6436 | click or scan EU-EC-10010850431 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6437 | click or scan EU-EC-10010850389 | | 2021-12-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6438 | click or scan EU-EC-10010850264 | | 2021-12-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Anaemia (n/a - Unknown - ), Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Bedridden (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - ), Diaphragm muscle weakness (n/a - Unknown - ), Diaphragmalgia (n/a - Unknown - Other Medically Important Condition), Dyspepsia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysuria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eructation (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Functional gastrointestinal disorder (n/a - Unknown - ), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Grip strength decreased (n/a - Unknown - ), Hypersomnia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Incontinence (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental impairment (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neuralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Organ failure (n/a - Unknown - ), PCO2 increased (n/a - Unknown - ), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Platelet disorder (n/a - Unknown - ), Renal impairment (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6439 | click or scan EU-EC-10010850036 | | 2021-12-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abnormal behaviour (n/a - Unknown - Disabling), Amnesia (n/a - Unknown - Disabling), Cognitive disorder (n/a - Unknown - Disabling), Dementia (n/a - Unknown - Disabling), Fatigue (n/a - Unknown - Disabling), Hypersomnia (n/a - Unknown - Disabling), Patient elopement (n/a - Unknown - Disabling), Personality change (n/a - Unknown - Disabling), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (S - Atrial fibrillation - n/a - [12y - n/a - n/a]) |
| 6440 | click or scan EU-EC-10010850000 | | 2021-12-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6441 | click or scan EU-EC-10010849997 | | 2021-12-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6442 | click or scan EU-EC-10010849750 | | 2021-12-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6443 | click or scan EU-EC-10010849511 | | 2021-12-03 | Healthcare Professional | EEA | More than 85 Years | Male | Ascites (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Immobile (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 6444 | click or scan EU-EC-10010849466 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6445 | click or scan EU-EC-10010848884 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6446 | click or scan EU-EC-10010848697 | | 2021-12-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cough (n/a - Unknown - ), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site erythema (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 6447 | click or scan EU-EC-10010848377 | | 2021-12-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), REVLIMID [LENALIDOMIDE] (S - Plasma cell myeloma - Drug withdrawn - [18d - 10mg - Oral]), [HYALURONIDASE, HISTIDINE, METHIONINE, HISTIDINE HYDROCHLORIDE MONOHYDRATE, POLYSORBATE 20, SORBITOL (E420), DARATUMUMAB] (S - Plasma cell myeloma - Drug withdrawn - [n/a - 15mL - Subcutaneous]), [HYALURONIDASE, HISTIDINE, METHIONINE, HISTIDINE HYDROCHLORIDE MONOHYDRATE, POLYSORBATE 20, SORBITOL (E420), DARATUMUMAB] (S - n/a - Drug withdrawn - [n/a - 15mL - Subcutaneous]) |
| 6448 | click or scan EU-EC-10010848269 | | 2021-12-03 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| 6449 | click or scan EU-EC-10010848213 | | 2021-12-03 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 6450 | click or scan EU-EC-10010848207 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Female | Respiratory distress (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 6451 | click or scan EU-EC-10010848196 | | 2021-12-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]), [MIDAZOLAM] (S - Inguinal hernia - n/a - [1d - 4mg - Intravenous (not otherwise specified)]), [TRAMADOL HYDROCHLORIDE] (S - Analgesic intervention supportive therapy - n/a - [1d - 100mg - Intravenous drip]) |
| 6452 | click or scan EU-EC-10010848127 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 6453 | click or scan EU-EC-10010848088 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ascites (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6454 | click or scan EU-EC-10010848078 | | 2021-12-03 | Non Healthcare Professional | EEA | Not Specified | Male | Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Immobile (n/a - Unknown - Disabling), Inappropriate schedule of product administration (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6455 | click or scan EU-EC-10010848059 | | 2021-12-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac valve disease (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6456 | click or scan EU-EC-10010848058 | | 2021-12-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6457 | click or scan EU-EC-10010848041 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6458 | click or scan EU-EC-10010848040 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6459 | click or scan EU-EC-10010848029 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6460 | click or scan EU-EC-10010847905 | | 2021-12-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Encephalitis viral (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 6461 | click or scan EU-EC-10010847876 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6462 | click or scan EU-EC-10010847847 | | 2021-12-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Organ failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6463 | click or scan EU-EC-10010847688 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **6464** | click or scan<br>EU-EC-10010847672 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| **6465** | click or scan<br>EU-EC-10010847637 | | 2021-12-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **6466** | click or scan<br>EU-EC-10010847622 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (11min - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **6467** | click or scan<br>EU-EC-10010847555 | | 2021-12-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (2d - Recovered/Resolved - ), Injection site haematoma (11d - Recovered/Resolved - ), Myalgia (2d - Recovered/Resolved - ) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **6468** | click or scan<br>EU-EC-10010847393 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood fibrinogen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebellar ataxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nervous system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Personality change (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6469 | click or scan EU-EC-10010847381 | | 2021-12-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6470 | click or scan EU-EC-10010847303 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6471 | click or scan EU-EC-10010847239 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6472 | click or scan EU-EC-10010847189 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Eyelid ptosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Liver disorder (n/a - Recovered/Resolved - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Myasthenia gravis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Rhabdomyolysis (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6473 | click or scan EU-EC-10010847186 | | 2021-12-03 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6474 | click or scan EU-EC-10010847099 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6475 | click or scan EU-EC-10010847051 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6476 | click or scan EU-EC-10010846994 | | 2021-12-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6477 | click or scan EU-EC-10010846961 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6478 | click or scan EU-EC-10010846948 | | 2021-12-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6479 | click or scan EU-EC-10010846916 | | 2021-12-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6480 | click or scan EU-EC-10010846765 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6481 | click or scan EU-EC-10010846750 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6482 | click or scan EU-EC-10010846640 | | 2021-12-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6483 | click or scan EU-EC-10010846630 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6484 | click or scan EU-EC-10010846564 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Female | Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6485 | click or scan EU-EC-10010846564 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Female | Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6486 | click or scan EU-EC-10010846370 | | 2021-12-03 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6487 | click or scan EU-EC-10010846336 | | 2021-12-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6488 | click or scan EU-EC-10010846260 | | 2021-12-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 6489 | click or scan EU-EC-10010846154 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6490 | click or scan EU-EC-10010846134 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Abnormal behaviour (n/a - Unknown - ), Breath sounds abnormal (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Torticollis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6491 | click or scan EU-EC-10010846127 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6492 | click or scan EU-EC-10010846118 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral haematoma (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6493 | click or scan EU-EC-10010846101 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6494 | click or scan EU-EC-10010846088 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6495 | click or scan EU-EC-10010846071 | | 2021-12-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abdominal tenderness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Focal peritonitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritoneal perforation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6496 | click or scan EU-EC-10010846052 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (0d - Recovered/Resolved - Life Threatening), Cerebral infarction (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Metabolic acidosis (n/a - Unknown - Life Threatening), Post cardiac arrest syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Ventricular tachycardia (0d - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6497 | click or scan EU-EC-10010846045 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6498 | click or scan EU-EC-10010846038 | | 2021-12-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Suspected counterfeit product (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6499 | click or scan EU-EC-10010846036 | | 2021-12-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Eczema (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6500 | click or scan EU-EC-10010845958 | | 2021-12-03 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6501 | click or scan EU-EC-10010845795 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6502 | click or scan EU-EC-10010845787 | | 2021-12-03 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6503 | click or scan EU-EC-10010844936 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6504 | click or scan EU-EC-10010844881 | | 2021-12-03 | Healthcare Professional | EEA | More than 85 Years | Female | Peripheral artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 6505 | click or scan EU-EC-10010844866 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6506 | click or scan EU-EC-10010844492 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6507 | click or scan EU-EC-10010844202 | | 2021-12-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6508 | click or scan EU-EC-10010843559 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6509 | click or scan EU-EC-10010843446 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fraction of inspired oxygen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrostomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia necrotising (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia pseudomonal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive end-expiratory pressure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal tubular necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tidal volume (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tracheostomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6510 | click or scan EU-EC-10010843398 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6511 | click or scan EU-EC-10010842901 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |
| 6512 | click or scan EU-EC-10010842758 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Electrolyte imbalance (n/a - Unknown - ), Hepatic function abnormal (n/a - Unknown - ), Hyperglycaemia (n/a - Unknown - ), Hyperkalaemia (n/a - Unknown - Other Medically Important Condition), Hyponatraemia (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Shock (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6513 | click or scan EU-EC-10010842749 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Activated partial thromboplastin time prolonged (5d - Fatal - **Results in Death**), Acute kidney injury (5d - Fatal - **Results in Death**, Other Medically Important Condition), Alanine aminotransferase increased (5d - Fatal - **Results in Death**), Anion gap normal (5d - Fatal - **Results in Death**), Anticoagulant therapy (5d - Fatal - **Results in Death**), Aspartate aminotransferase increased (5d - Fatal - **Results in Death**), Atrial fibrillation (5d - Fatal - **Results in Death**, Other Medically Important Condition), Basophil percentage decreased (5d - Fatal - **Results in Death**), Blood albumin decreased (5d - Fatal - **Results in Death**), Blood alkaline phosphatase normal (5d - Fatal - **Results in Death**), Blood bilirubin normal (5d - Fatal - **Results in Death**), Blood calcium decreased (5d - Fatal - **Results in Death**), Blood chloride increased (5d - Fatal - **Results in Death**), Blood creatinine increased (5d - Fatal - **Results in Death**), Blood glucose abnormal (5d - Fatal - **Results in Death**), Blood lactate dehydrogenase increased (5d - Fatal - **Results in Death**), Blood phosphorus decreased (5d - Fatal - **Results in Death**), Blood potassium increased (5d - Fatal - **Results in Death**), Blood sodium normal (5d - Fatal - **Results in Death**), Blood urea increased (5d - Fatal - **Results in Death**), Brain natriuretic peptide increased (5d - Fatal - **Results in Death**), COVID-19 (5d - Fatal - **Results in Death**), Carbon dioxide decreased (5d - Fatal - **Results in Death**), Cardiac failure congestive (5d - Fatal - **Results in Death**, Other Medically Important Condition), Chest X-ray (5d - Fatal - **Results in Death**), Chronic kidney disease (5d - Fatal - **Results in Death**, Other Medically Important Condition), Differential white blood cell count (5d - Fatal - **Results in Death**), Eosinophil percentage decreased (5d - Fatal - **Results in Death**), Full blood count (5d - Fatal - **Results in Death**), Glomerular filtration rate decreased (5d - Fatal - **Results in Death**), Haematocrit decreased (5d - Fatal - **Results in Death**), Haemoglobin decreased (5d - Fatal - **Results in Death**), Hypoxia (5d - Fatal - **Results in Death**, Other Medically Important Condition), Laboratory test (5d - Fatal - **Results in Death**), Laboratory test abnormal (5d - Fatal - **Results in Death**), Lymphocyte count decreased (5d - Fatal - **Results in Death**), Lymphocyte percentage decreased (5d - Fatal - **Results in Death**), Mean cell haemoglobin concentration normal (5d - Fatal - **Results in Death**), Mean cell haemoglobin normal (5d - Fatal - **Results in Death**), Mean cell volume normal (5d - Fatal - **Results in Death**), Mean platelet volume normal (5d - Fatal - **Results in Death**), Monocyte count (5d - Fatal - **Results in Death**), Monocyte percentage (5d - Fatal - **Results in Death**), Myocardial injury (5d - Fatal - **Results in Death**, Other Medically Important Condition), Neutrophil count (5d - Fatal - **Results in Death**), Neutrophil percentage increased (5d - Fatal - **Results in Death**), Platelet count normal (5d - Fatal - **Results in Death**), Protein total decreased (5d - Fatal - **Results in Death**), Red blood cell count decreased (5d - Fatal - **Results in Death**), Red cell distribution width increased (5d - Fatal - **Results in Death**), Renal failure (5d - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (5d - Fatal - **Results in Death**), Troponin I increased (5d - Fatal - **Results in Death**), White blood cell count normal (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6514 | click or scan EU-EC-10010842615 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6515 | click or scan EU-EC-10010842603 | | 2021-12-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6516 | click or scan EU-EC-10010842373 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6517 | click or scan EU-EC-10010842231 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 6518 | click or scan EU-EC-10010841618 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **6519** | click or scan EU-EC-10010841445 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6520** | click or scan EU-EC-10010841440 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **6521** | click or scan EU-EC-10010841409 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| **6522** | click or scan EU-EC-10010841274 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Heart valve incompetence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **6523** | click or scan EU-EC-10010841098 | | 2021-12-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute hepatic failure (n/a - Fatal - **Results in Death**), Acute left ventricular failure (n/a - Fatal - **Results in Death**), Angiogram cerebral abnormal (n/a - Fatal - **Results in Death**), Brain death (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Distributive shock (n/a - Fatal - **Results in Death**), Echocardiogram abnormal (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Hyperammonaemia (n/a - Fatal - **Results in Death**), Hyperventilation (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Intracranial pressure increased (n/a - Fatal - **Results in Death**), Laboratory test (n/a - Fatal - **Results in Death**), Lactic acidosis (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pupil fixed (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **6524** | click or scan EU-EC-10010841063 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **6525** | click or scan EU-EC-10010841045 | | 2021-12-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6526 | click or scan EU-EC-10010841017 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (16d - Fatal - **Results in Death**), Peripheral swelling (16d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 6527 | click or scan EU-EC-10010841000 | | 2021-12-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Discomfort (n/a - Unknown - ), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Unknown - ), Off label use (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6528 | click or scan EU-EC-10010840924 | | 2021-12-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6529 | click or scan EU-EC-10010840769 | | 2021-12-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6530 | click or scan EU-EC-10010840649 | | 2021-12-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6531 | click or scan EU-EC-10010840081 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Myocardial ischaemia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 6532 | click or scan EU-EC-10010840046 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Female | Hypotension (n/a - Fatal - **Results in Death**), Metabolic acidosis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .25mL - Intramuscular]) |
| 6533 | click or scan EU-EC-10010839607 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Male | Autoimmune disorder (n/a - Fatal - **Results in Death**), Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6534 | click or scan EU-EC-10010839592 | | 2021-12-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6535 | click or scan EU-EC-10010839578 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6536 | click or scan EU-EC-10010839574 | | 2021-12-03 | Non Healthcare Professional | EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6537 | click or scan EU-EC-10010839290 | | 2021-12-03 | Healthcare Professional | EEA | 18-64 Years | Male | Autoimmune disorder (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Joint swelling (n/a - Unknown - ), Skin reaction (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6538 | click or scan EU-EC-10010839379 | | 2021-12-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6539 | click or scan EU-EC-10010839191 | | 2021-12-02 | Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercalcaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxicity to various agents (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [METHOTREXATE] (S - Rheumatoid arthritis - Drug withdrawn - [n/a - 25mg - Subcutaneous]) |
| 6540 | click or scan EU-EC-10010839097 | | 2021-12-02 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 6541 | click or scan EU-EC-10010838737 | | 2021-12-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - ), Paranoia (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6542 | click or scan EU-EC-10010838484 | | 2021-12-02 | Healthcare Professional | EEA | Not Specified | Not Specified | Trisomy 18 (82d - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Transplacental]) |
| 6543 | click or scan EU-EC-10010838381 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (2d - Fatal - **Results in Death**), Cold sweat (2d - Fatal - **Results in Death**), Gait inability (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6544 | click or scan EU-EC-10010837930 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6545 | click or scan EU-EC-10010837927 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pain in extremity (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 6546 | click or scan EU-EC-10010837165 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6547 | click or scan EU-EC-10010837137 | | 2021-12-02 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Abortion spontaneous (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 6548 | click or scan EU-EC-10010837047 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Neutrophilia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6549 | click or scan EU-EC-10010836988 | | 2021-12-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6550 | click or scan EU-EC-10010836799 | | 2021-12-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6551 | click or scan EU-EC-10010836436 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Nasal congestion (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6552 | click or scan EU-EC-10010836346 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**), Haemolysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| | | | | | | | | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN, A/BRISBANE/10/2007 (H3N2)-LIKE STRAIN, B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1) VREASS. X - 179 A, A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/HONG |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT (Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route) |
|---|---|---|---|---|---|---|---|---|---|
| 6553 | click or scan<br><br>EU-EC-10010835764 | | 2021-12-02 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, NIB-104), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/NANCHANG/933/95 (H3N2), A/BAYERN/7/95 (H1N1) - LIKE STRAIN (A/JOHANNESBURG/82/96), B/BEIJING/184/93-LIKE STRAIN (B/HARBIN/7/94), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/CALIFORNIA/7/2004 (H3N2) - LIKE STRAIN (A/NEW YORK/55/2004 REASS. NYMC X-157), B/SHANGHAI/361/2002 - LIKE STRAIN (B/JIANGSU/10/2003), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/MOSCOW/10/99 (H3N2) - LIKE STRAIN (A/PANAMA/2007/99 REASS. RESVIR-17), B/SICHUAN/379/99-LIKE STRAIN (B/JOHANNESBURG/5/99), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)-DERIVED STRAIN USED NYMC X-181, B/BRISBANE/60/2008, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN B, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1)V-LIKE VIRUS, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)] |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017(H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327), B/MASSACHUSETTS/2/2012 -DERIVED STRAIN USED (NYMC BX-51B), A/TEXAS/50/2012 (H3N2) |
| | | | | | | | | | â€“ DERIVED STRAIN USED (NYMC X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), B/MASSACHUSETTS/2/2012 -DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN A (H1N1), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN A (H3N2), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN B] (S - Influenza immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **6554** | click or scan EU-EC-10010835633 | | 2021-12-02 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **6555** | click or scan EU-EC-10010835563 | | 2021-12-02 | Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **6556** | click or scan EU-EC-10010835393 | | 2021-12-02 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [84d - 1 {DF} - Intramuscular]) |
| **6557** | click or scan EU-EC-10010835265 | | 2021-12-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **6558** | click or scan EU-EC-10010835262 | | 2021-12-02 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **6559** | click or scan EU-EC-10010835255 | | 2021-12-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **6560** | click or scan EU-EC-10010835236 | | 2021-12-02 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6561 | click or scan EU-EC-10010835211 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6562 | click or scan EU-EC-10010835191 | | 2021-12-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not Resolved - ), Tremor (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6563 | click or scan EU-EC-10010835186 | | 2021-12-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6564 | click or scan EU-EC-10010834969 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atrioventricular block second degree (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Cold sweat (n/a - Unknown - ), Gaze palsy (n/a - Unknown - ), Myotonic dystrophy (n/a - Fatal - **Results in Death**), Petit mal epilepsy (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6565 | click or scan EU-EC-10010834943 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6566 | click or scan EU-EC-10010834352 | | 2021-12-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Interchange of vaccine products (1d - Recovered/Resolved - ), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6567 | click or scan EU-EC-10010833748 | | 2021-12-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myeloid leukaemia (98d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood disorder (98d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood iron decreased (98d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (98d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immediate post-injection reaction (98d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (98d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6568 | click or scan EU-EC-10010833742 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6569 | click or scan EU-EC-10010833741 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypopnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6570 | click or scan EU-EC-10010833737 | | 2021-12-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6571 | click or scan EU-EC-10010833453 | | 2021-12-02 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6572 | click or scan EU-EC-10010833426 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - ), Vaccine breakthrough infection (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 6573 | click or scan EU-EC-10010833277 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6574 | click or scan EU-EC-10010833103 | | 2021-12-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 6575 | click or scan EU-EC-10010833087 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ammonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cytogenetic analysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemofiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ornithine transcarbamoylase deficiency (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6576 | click or scan EU-EC-10010833079 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6577 | click or scan EU-EC-10010833035 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6578 | click or scan EU-EC-10010832995 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |
| 6579 | click or scan EU-EC-10010832979 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6580 | click or scan EU-EC-10010832816 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6581 | click or scan EU-EC-10010832790 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6582 | click or scan EU-EC-10010832776 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Life support (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse abnormal (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6583 | click or scan EU-EC-10010832748 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6584 | click or scan EU-EC-10010832738 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6585 | click or scan EU-EC-10010832727 | | 2021-12-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (16d - Fatal - **Results in Death**), Death (16d - Fatal - **Results in Death**), SARS-CoV-2 test positive (16d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6586 | click or scan EU-EC-10010832664 | | 2021-12-02 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6587 | click or scan EU-EC-10010832620 | | 2021-12-02 | Healthcare Professional | EEA | Not Specified | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 6588 | click or scan EU-EC-10010832352 | | 2021-12-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Anger (n/a - Unknown - Caused/Prolonged Hospitalisation), Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhagic stroke (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Illness (n/a - Unknown - Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mood swings (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - ), Ruptured cerebral aneurysm (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Strabismus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6589 | click or scan EU-EC-10010832328 |  | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aneurysm ruptured (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Apnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial aneurysm (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intraventricular haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urticaria (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6590 | click or scan EU-EC-10010832312 |  | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6591 | click or scan EU-EC-10010832308 |  | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6592 | click or scan EU-EC-10010832295 |  | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6593 | click or scan EU-EC-10010832248 |  | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6594 | click or scan EU-EC-10010832242 |  | 2021-12-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6595 | click or scan EU-EC-10010832221 |  | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tumour embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **6596** | click or scan EU-EC-10010831971 |  | 2021-12-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **6597** | click or scan EU-EC-10010831970 |  | 2021-12-02 | Healthcare Professional | EEA | More than 85 Years | Male | Fall (n/a - Unknown - ), Herpes zoster (n/a - Unknown - ), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **6598** | click or scan EU-EC-10010831947 |  | 2021-12-02 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **6599** | click or scan EU-EC-10010831907 |  | 2021-12-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **6600** | click or scan EU-EC-10010831702 |  | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain hypoxia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **6601** | click or scan EU-EC-10010831578 |  | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Erythema (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Inflammation (n/a - Unknown - ), Intestinal ischaemia (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - ), Sleep disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **6602** | click or scan EU-EC-10010830289 |  | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **6603** | click or scan EU-EC-10010830008 |  | 2021-12-02 | Healthcare Professional | EEA | 65-85 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**), Oral pain (n/a - Fatal - **Results in Death**), Osteitis (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **6604** | click or scan EU-EC-10010828867 |  | 2021-12-02 | Non Healthcare Professional | EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **6605** | click or scan EU-EC-10010828712 |  | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6606 | click or scan EU-EC-10010828657 | | 2021-12-02 | Healthcare Professional | EEA | 18-64 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**, Life Threatening), Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6607 | click or scan EU-EC-10010828644 | | 2021-12-02 | Non Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6608 | click or scan EU-EC-10010828643 | | 2021-12-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thalamus haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6609 | click or scan EU-EC-10010828618 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ileus paralytic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6610 | click or scan EU-EC-10010828141 | | 2021-12-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6611 | click or scan EU-EC-10010827984 | | 2021-12-02 | Non Healthcare Professional | EEA | Not Specified | Female | Concomitant disease aggravated (n/a - Unknown - ), Hepatic cancer (1mo - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6612 | click or scan EU-EC-10010827229 | | 2021-12-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Ascites (n/a - Unknown - Other Medically Important Condition), Brain cancer metastatic (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Hepatic cancer metastatic (n/a - Fatal - **Results in Death**), Hepatic function abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatic carcinoma (n/a - Fatal - **Results in Death**), Rhabdomyolysis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6613 | click or scan EU-EC-10010827141 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Alveolar lung disease (n/a - Fatal - **Results in Death**), Anaphylactic reaction (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Heat illness (n/a - Unknown - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6614 | click or scan EU-EC-10010826719 | | 2021-12-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sinus tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 6615 | click or scan EU-EC-10010826253 | | 2021-12-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6616 | click or scan EU-EC-10010825304 | | 2021-12-02 | Non Healthcare Professional | EEA | More than 85 Years | Male | Hepatic failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6617 | click or scan EU-EC-10010824155 | | 2021-12-01 | Healthcare Professional | EEA | 65-85 Years | Female | Depressed mood (n/a - Recovering/Resolving - ), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Sudden death (4d - Fatal - **Results in Death**), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6618 | click or scan EU-EC-10010823767 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6619 | click or scan EU-EC-10010823192 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Parkinson's disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6620 | click or scan EU-EC-10010823168 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Alanine aminotransferase normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anion gap (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anisocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Band neutrophil percentage increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood albumin normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood alkaline phosphatase normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bilirubin normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood chloride normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain natriuretic peptide normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bronchoscopy abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Carbon dioxide normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardioversion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central venous catheterisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Differential white blood cell count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6621 | click or scan EU-EC-10010822671 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6622 | click or scan EU-EC-10010822608 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia bacterial (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superinfection (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6623 | click or scan EU-EC-10010822593 | | 2021-12-01 | Healthcare Professional | EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 6624 | click or scan EU-EC-10010822571 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6625 | click or scan EU-EC-10010822553 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6626 | click or scan EU-EC-10010822457 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6627 | click or scan EU-EC-10010822333 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Road traffic accident (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6628 | click or scan EU-EC-10010822316 | | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood bicarbonate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood electrolytes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood magnesium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pH decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood phosphorus increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoacusis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6629 | click or scan EU-EC-10010822309 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Breast cancer female (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6630 | click or scan EU-EC-10010822308 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6631 | click or scan EU-EC-10010822099 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6632 | click or scan EU-EC-10010822032 | | 2021-12-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6633 | click or scan EU-EC-10010822018 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6634 | click or scan EU-EC-10010821794 | | 2021-12-01 | Healthcare Professional | EEA | 65-85 Years | Male | Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6635 | click or scan EU-EC-10010821762 | | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6636 | click or scan EU-EC-10010820920 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6637 | click or scan EU-EC-10010820794 | | 2021-12-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Immunisation (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6638 | click or scan EU-EC-10010820792 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6639 | click or scan EU-EC-10010820743 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac aneurysm (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6640 | click or scan EU-EC-10010820593 | | 2021-12-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 6641 | click or scan EU-EC-10010820588 | | 2021-12-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Left ventricular dysfunction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| 6642 | click or scan EU-EC-10010820573 | | 2021-12-01 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**), Vomiting (1d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, X-181), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), B/MASSACHUSETTS/2/2012-LIKE STRAIN (B/MASSACHUSETTS/2/2012, BX-51B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B)] (S - Influenza immunisation - Not applicable - [1d - .5mL - Subcutaneous]) |
| 6643 | click or scan EU-EC-10010820569 | | 2021-12-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (1h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 6644 | click or scan EU-EC-10010820492 | | 2021-12-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (27d - Fatal - **Results in Death**), Vaccination failure (27d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [25d - 2{DF} - Intramuscular]), [LOSARTAN POTASSIUM] (S - Hypertension - n/a - [n/a - 1{DF} - Oral]) |
| 6645 | click or scan EU-EC-10010820390 | | 2021-12-01 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (2wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 6646 | click or scan EU-EC-10010820298 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dementia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (1d - Fatal - **Results in Death**), General physical condition abnormal (1d - Fatal - **Results in Death**), Pallor (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6647 | click or scan EU-EC-10010820242 | | 2021-12-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Vertigo (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6648 | click or scan EU-EC-10010820099 | | 2021-12-01 | Healthcare Professional | EEA | 18-64 Years | Male | Body temperature increased (1d - Unknown - ), Cardiac tamponade (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6649 | click or scan EU-EC-10010820017 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eye movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary artery wall hypertrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6650 | click or scan EU-EC-10010819656 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic valve incompetence (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Blood corticotrophin normal (n/a - Fatal - **Results in Death**), Cardiac pacemaker insertion (n/a - Fatal - **Results in Death**), Catheter placement (n/a - Fatal - **Results in Death**), Central venous catheterisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Echocardiogram (n/a - Fatal - **Results in Death**), Echocardiogram abnormal (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Fatal - **Results in Death**), Endocarditis (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Haemodialysis (n/a - Fatal - **Results in Death**), Hepatorenal syndrome (n/a - Fatal - **Results in Death**), Hypoperfusion (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Streptococcal bacteraemia (n/a - Fatal - **Results in Death**), Torsade de pointes (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6651 | click or scan EU-EC-10010819564 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6652 | click or scan EU-EC-10010819517 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Orthopnoea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6653 | click or scan EU-EC-10010819455 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysgraphia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysstasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Insomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6654 | click or scan EU-EC-10010819311 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 6655 | click or scan EU-EC-10010818832 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - .3mL - Intramuscular]) |
| 6656 | click or scan EU-EC-10010818804 | | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6657 | click or scan EU-EC-10010818801 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - .3mL - Intramuscular]) |
| 6658 | click or scan EU-EC-10010818613 | | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Immunisation (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6659 | click or scan EU-EC-10010818601 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**), Concomitant disease aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6660 | click or scan EU-EC-10010818595 | | 2021-12-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - ), Lip discolouration (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6661 | click or scan EU-EC-10010818562 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6662 | click or scan EU-EC-10010818561 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6663 | click or scan EU-EC-10010818551 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**), Troponin abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6664 | click or scan EU-EC-10010818540 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6665 | click or scan EU-EC-10010818222 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6666 | click or scan EU-EC-10010818098 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6667 | click or scan EU-EC-10010818053 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6668 | click or scan EU-EC-10010818041 | | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6669 | click or scan EU-EC-10010817299 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6670 | click or scan EU-EC-10010817238 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6671 | click or scan EU-EC-10010817140 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac index decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Catheterisation cardiac abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Essential hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6672 | click or scan EU-EC-10010817037 | | 2021-12-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6673 | click or scan EU-EC-10010816944 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain scan abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea haemorrhagic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injected limb mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6674 | click or scan EU-EC-10010816927 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6675 | click or scan EU-EC-10010816922 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6676 | click or scan EU-EC-10010816921 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6677 | click or scan EU-EC-10010816869 | | 2021-12-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6678 | click or scan EU-EC-10010816608 |  | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Debridement (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Extubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Necrotising fasciitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Supraventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6679 | click or scan EU-EC-10010816607 |  | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6680 | click or scan EU-EC-10010816605 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6681 | click or scan EU-EC-10010816597 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acinetobacter bacteraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Axillary vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cognitive disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electroencephalogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Goitre (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jugular vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological examination (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary artery dilatation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Scan with contrast abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6682 | click or scan EU-EC-10010816596 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Blood creatinine increased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6683 | click or scan EU-EC-10010816498 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematochezia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6684 | click or scan EU-EC-10010816487 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6685 | click or scan EU-EC-10010816486 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6686 | click or scan EU-EC-10010816454 |  | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), X-ray (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6687 | click or scan EU-EC-10010816432 |  | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute lymphocytic leukaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bleeding time (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Increased tendency to bruise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 6688 | click or scan EU-EC-10010816427 |  | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6689 | click or scan EU-EC-10010816421 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6690 | click or scan EU-EC-10010816412 |  | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6691 | click or scan EU-EC-10010816402 |  | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6692 | click or scan EU-EC-10010816352 | | 2021-12-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6693 | click or scan EU-EC-10010816282 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Type 1 diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 6694 | click or scan EU-EC-10010816277 | | 2021-12-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6695 | click or scan EU-EC-10010816182 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 6696 | click or scan EU-EC-10010816181 | | 2021-12-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6697 | click or scan EU-EC-10010815734 | | 2021-12-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Epilepsy (65d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypertension (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pneumonia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Urinary tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6698 | click or scan EU-EC-10010814079 | | 2021-12-01 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6699 | click or scan EU-EC-10010813962 | | 2021-12-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anal incontinence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Bedridden (n/a - Not Recovered/Not Resolved - Disabling), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Inflammation (n/a - Not Recovered/Not Resolved - ), Lung cancer metastatic (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Weight decreased (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6700 | click or scan EU-EC-10010813817 | | 2021-12-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Kidney infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6701 | click or scan EU-EC-10010813612 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6702 | click or scan EU-EC-10010812733 | | 2021-12-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acidosis (n/a - Unknown - Other Medically Important Condition), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), INVEGA [PALIPERIDONE] (S - n/a - Not applicable - [n/a - n/a - Oral]) |
| 6703 | click or scan EU-EC-10010812606 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Exposure to toxic agent (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**), Poor quality product administered (n/a - Fatal - **Results in Death**), Product contamination chemical (n/a - Fatal - **Results in Death**), Product contamination microbial (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6704 | click or scan EU-EC-10010812576 | | 2021-12-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6705 | click or scan EU-EC-10010810981 | | 2021-12-01 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (51d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 6706 | click or scan EU-EC-10010810597 | | 2021-11-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bacteroides bacteraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile neutropenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemophagocytic lymphohistiocytosis (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Liver injury (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6707 | click or scan EU-EC-10010810062 | | 2021-11-30 | Healthcare Professional | EEA | More than 85 Years | Male | Dizziness (2d - Fatal - **Results in Death**), Hypertension (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 6708 | click or scan EU-EC-10010809147 | | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 6709 | click or scan EU-EC-10010808943 | | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6710 | click or scan EU-EC-10010808683 | | 2021-11-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6711 | click or scan EU-EC-10010808498 | | 2021-11-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Recovering/Resolving - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - ), Dysstasia (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Gait inability (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Heart rate increased (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Pain (n/a - Recovering/Resolving - ), Platelet count decreased (n/a - Recovering/Resolving - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6712 | click or scan EU-EC-10010807658 | | 2021-11-30 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain oedema (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiogenic shock (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coronary ostial stenosis (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6713 | click or scan EU-EC-10010807643 | | 2021-11-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6714 | click or scan EU-EC-10010807638 | | 2021-11-30 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 6715 | click or scan EU-EC-10010807611 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6716 | click or scan EU-EC-10010807601 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6717 | click or scan EU-EC-10010807596 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6718 | click or scan EU-EC-10010807594 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6719 | click or scan EU-EC-10010807590 | | 2021-11-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6720 | click or scan EU-EC-10010807544 | | 2021-11-30 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [25d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6721 | click or scan EU-EC-10010807528 |  | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1 {DF} - Intramuscular]) |
| 6722 | click or scan EU-EC-10010807417 |  | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (15d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 6723 | click or scan EU-EC-10010805948 |  | 2021-11-30 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6724 | click or scan EU-EC-10010805907 |  | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6725 | click or scan EU-EC-10010805472 |  | 2021-11-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6726 | click or scan EU-EC-10010805470 |  | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6727 | click or scan EU-EC-10010805431 |  | 2021-11-30 | Non Healthcare Professional | EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6728 | click or scan EU-EC-10010805429 |  | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6729 | click or scan EU-EC-10010805115 |  | 2021-11-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foaming at mouth (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6730 | click or scan EU-EC-10010805069 |  | 2021-11-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6731 | click or scan EU-EC-10010804988 | | 2021-11-30 | Healthcare Professional | EEA | More than 85 Years | Male | C-reactive protein increased (0d - Fatal - **Results in Death**), Cerebral haemorrhage (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Fibrin D dimer increased (0d - Fatal - **Results in Death**), Prothrombin time shortened (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6732 | click or scan EU-EC-10010804640 | | 2021-11-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6733 | click or scan EU-EC-10010804106 | | 2021-11-30 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6734 | click or scan EU-EC-10010803447 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (9d - Fatal - **Results in Death**), Fatigue (9d - Fatal - **Results in Death**), Malaise (9d - Fatal - **Results in Death**), Myocardial necrosis marker increased (9d - Fatal - **Results in Death**), Prosthetic cardiac valve thrombosis (9d - Fatal - **Results in Death**), Renal impairment (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6735 | click or scan EU-EC-10010803399 | | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE)] (S - Influenza immunisation - n/a - [n/a - .7mL - Intramuscular]) |
| 6736 | click or scan EU-EC-10010803103 | | 2021-11-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6737 | click or scan EU-EC-10010803024 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Spinal stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6738 | click or scan EU-EC-10010802924 | | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Not Recovered/Not Resolved - ), Arthralgia (n/a - Recovered/Resolved - ), Sudden death (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Syncope (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6739 | click or scan EU-EC-10010802485 | | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6740 | click or scan EU-EC-10010802320 | | 2021-11-30 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 6741 | click or scan EU-EC-10010802254 | | 2021-11-30 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6742 | click or scan EU-EC-10010802250 | | 2021-11-30 | Healthcare Professional | EEA | 65-85 Years | Female | Bronchial wall thickening (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Emphysema (n/a - Fatal - **Results in Death**), Hilar lymphadenopathy (n/a - Fatal - **Results in Death**), Hyponatraemia (n/a - Fatal - **Results in Death**), Lung consolidation (n/a - Fatal - **Results in Death**), Lung infiltration (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Paratracheal lymphadenopathy (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6743 | click or scan EU-EC-10010802206 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac dysfunction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac ventricular thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 6744 | click or scan EU-EC-10010802203 | | 2021-11-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6745 | click or scan EU-EC-10010802195 | | 2021-11-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Paralysis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6746 | click or scan EU-EC-10010801956 | | 2021-11-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6747 | click or scan EU-EC-10010801879 | | 2021-11-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Faeces discoloured (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Gastric cancer (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6748 | click or scan EU-EC-10010801869 | | 2021-11-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6749 | click or scan EU-EC-10010801630 | | 2021-11-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6750 | click or scan EU-EC-10010800633 | | 2021-11-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6751 | click or scan EU-EC-10010800450 | | 2021-11-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6752 | click or scan EU-EC-10010800329 | | 2021-11-30 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 6753 | click or scan EU-EC-10010800200 | | 2021-11-30 | Healthcare Professional | EEA | Not Specified | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6754 | click or scan EU-EC-10010799968 | | 2021-11-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6755 | click or scan EU-EC-10010799275 | | 2021-11-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 6756 | click or scan EU-EC-10010799247 | | 2021-11-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Leukopenia (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6757 | click or scan EU-EC-10010799197 | | 2021-11-30 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6758 | click or scan EU-EC-10010796559 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Acute kidney injury (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Vision blurred (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6759 | click or scan EU-EC-10010796194 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Foetal death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6760 | click or scan EU-EC-10010796074 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6761 | click or scan EU-EC-10010795871 | | 2021-11-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Inflammation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6762 | click or scan EU-EC-10010795769 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6763 | click or scan EU-EC-10010795738 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Arrhythmia (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Recovering/Resolving - ), Cyanosis (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6764 | click or scan EU-EC-10010795457 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6765 | click or scan EU-EC-10010795365 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6766 | click or scan EU-EC-10010794972 | | 2021-11-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6767 | click or scan EU-EC-10010794805 | | 2021-11-29 | Healthcare Professional | EEA | Not Specified | Not Specified | Congenital absence of cranial vault (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Transplacental]) |
| 6768 | click or scan EU-EC-10010794729 | | 2021-11-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6769 | click or scan EU-EC-10010794718 | | 2021-11-29 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6770 | click or scan EU-EC-10010794704 | | 2021-11-29 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - n/a - Intramuscular]) |
| 6771 | click or scan EU-EC-10010793989 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6772 | click or scan EU-EC-10010793596 | | 2021-11-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Product use issue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA VIRUS] (S - Immunisation - Not applicable - [1d - n/a - n/a]) |
| 6773 | click or scan EU-EC-10010793580 | | 2021-11-29 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6774 | click or scan EU-EC-10010793579 | | 2021-11-29 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (66d - Fatal - **Results in Death**), Autonomic nervous system imbalance (66d - Fatal - **Results in Death**), Balance disorder (66d - Fatal - **Results in Death**), Bedridden (66d - Fatal - **Results in Death**), Central nervous system lesion (66d - Fatal - **Results in Death**), Cognitive disorder (66d - Fatal - **Results in Death**), Death (66d - Fatal - **Results in Death**), Feeling abnormal (66d - Fatal - **Results in Death**), Motor dysfunction (66d - Fatal - **Results in Death**), Nervous system disorder (66d - Fatal - **Results in Death**), Prion disease (66d - Fatal - **Results in Death**), Skin disorder (66d - Fatal - **Results in Death**), Speech disorder (66d - Fatal - **Results in Death**), Spontaneous haematoma (66d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6775 | click or scan EU-EC-10010793483 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6776 | click or scan EU-EC-10010793454 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Carotid artery dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Migraine (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Sensory disturbance (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6777 | click or scan EU-EC-10010793450 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6778 | click or scan EU-EC-10010793446 | | 2021-11-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Diabetes mellitus (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6779 | click or scan EU-EC-10010793377 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6780 | click or scan EU-EC-10010793256 | | 2021-11-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (100d - Fatal - **Results in Death**), Thrombocytopenia (100d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6781 | click or scan EU-EC-10010792520 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6782 | click or scan EU-EC-10010792448 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [INFLUENZA QUADRIVALENT VACCINE (RDNA)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 6783 | click or scan EU-EC-10010792306 | | 2021-11-29 | Healthcare Professional | Non EEA | Not Specified | Male | Foetal hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 6784 | click or scan EU-EC-10010792260 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abnormal behaviour (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Migraine (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6785 | click or scan EU-EC-10010792245 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic myeloid leukaemia (n/a - Unknown - Other Medically Important Condition), Feeding disorder (n/a - Unknown - ), Headache (n/a - Unknown - ), Myeloproliferative neoplasm (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - ), Platelet count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Thrombocytosis (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vomiting (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6786 | click or scan EU-EC-10010792063 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6787 | click or scan EU-EC-10010792041 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6788 | click or scan EU-EC-10010792019 | | 2021-11-29 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6789 | click or scan EU-EC-10010792010 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pruritus (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Rash pruritic (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6790 | click or scan EU-EC-10010791997 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6791 | click or scan EU-EC-10010791943 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6792 | click or scan EU-EC-10010791011 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6793 | click or scan EU-EC-10010789995 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6794 | click or scan EU-EC-10010789994 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 6795 | click or scan EU-EC-10010789880 | | 2021-11-29 | Healthcare Professional | EEA | 18-64 Years | Male | Foetal cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6796 | click or scan EU-EC-10010789426 | | 2021-11-29 | Healthcare Professional | EEA | 18-64 Years | Male | Agonal respiration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Bronchitis bacterial (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Conduction disorder (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 6797 | click or scan EU-EC-10010789412 | | 2021-11-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (0d - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (0d - Recovered/Resolved - Other Medically Important Condition), Paralysis (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertigo (0d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6798 | click or scan EU-EC-10010789281 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6799 | click or scan EU-EC-10010788940 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood urine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6800 | click or scan EU-EC-10010788807 | | 2021-11-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6801 | click or scan EU-EC-10010788584 | | 2021-11-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 6802 | click or scan EU-EC-10010788328 | | 2021-11-29 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6803 | click or scan EU-EC-10010788280 | | 2021-11-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6804 | click or scan EU-EC-10010788120 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 6805 | click or scan EU-EC-10010787628 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6806 | click or scan EU-EC-10010786474 | | 2021-11-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6807 | click or scan EU-EC-10010786334 | | 2021-11-28 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (162d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **6808** | click or scan<br><br>EU-EC-10010786301 | | 2021-11-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), [A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, X-181), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), B/MASSACHUSETTS/2/2012-LIKE STRAIN (B/MASSACHUSETTS/2/2012, BX-51B), A/TEXAS/50/2012 (H3N2) â€“ DERIVED STRAIN USED (NYMC X-223A), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), B/MASSACHUSETTS/2/2012-LIKE STRAIN (B/MASSACHUSETTS/2/2012, BX-51B), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, NIB-104), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)] (S - n/a - n/a - [n/a - .5mL - Subcutaneous]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6809 | click or scan EU-EC-10010785561 | | 2021-11-28 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6810 | click or scan EU-EC-10010785509 | | 2021-11-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6811 | click or scan EU-EC-10010784034 | | 2021-11-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Brain death (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral mass effect (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Drug interaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Superior sagittal sinus thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | APIXABAN [APIXABAN] (S - Atrial fibrillation - Not applicable - [n/a - n/a - Unknown]), METHOTREXATE [METHOTREXATE] (I - Systemic lupus erythematosus - Drug withdrawn - [n/a - 25mg - Unknown]), RITUXIMAB [RITUXIMAB] (I - Systemic lupus erythematosus - Unknown - [n/a - n/a - Unknown]), TOZINAMERAN [TOZINAMERAN] (I - COVID-19 prophylaxis - Unknown - [n/a - n/a - Unknown]), TOZINAMERAN [TOZINAMERAN] (I - n/a - Unknown - [n/a - n/a - Unknown]) |
| 6812 | click or scan EU-EC-10010783446 | | 2021-11-27 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6813 | click or scan EU-EC-10010782717 | | 2021-11-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cellulitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6814 | click or scan EU-EC-10010782716 | | 2021-11-27 | Healthcare Professional | Non EEA | Not Specified | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6815 | click or scan EU-EC-10010782655 | | 2021-11-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6816 | click or scan EU-EC-10010782601 | | 2021-11-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage urinary tract (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administration error (n/a - Unknown - Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis in device (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary bladder haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6817 | click or scan EU-EC-10010782554 | | 2021-11-27 | Healthcare Professional | Non EEA | Not Specified | Female | Immune thrombocytopenia (7d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - 1mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6818 | click or scan EU-EC-10010781160 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6819 | click or scan EU-EC-10010780904 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (17h - Fatal - **Results in Death**), Death (30min - Fatal - **Results in Death**), Pyrexia (17h - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6820 | click or scan EU-EC-10010780750 | | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6821 | click or scan EU-EC-10010780585 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6822 | click or scan EU-EC-10010779716 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6823 | click or scan EU-EC-10010779295 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6824 | click or scan EU-EC-10010779206 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6825 | click or scan EU-EC-10010779087 | | 2021-11-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Nerve injury (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| 6826 | click or scan EU-EC-10010778555 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dysarthria (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 6827 | click or scan EU-EC-10010778378 | | 2021-11-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Arterial thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), T-cell type acute leukaemia (n/a - Fatal - **Results in Death**), Thrombophlebitis (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6828 | click or scan EU-EC-10010778376 | | 2021-11-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6829 | click or scan EU-EC-10010778370 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6830 | click or scan EU-EC-10010778281 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6831 | click or scan EU-EC-10010778151 | | 2021-11-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 6832 | click or scan EU-EC-10010778146 | | 2021-11-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 6833 | click or scan EU-EC-10010778050 | | 2021-11-26 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 6834 | click or scan EU-EC-10010778045 | | 2021-11-26 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory distress (0h - Fatal - **Results in Death**), Vasodilatation (0h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 6835 | click or scan EU-EC-10010777919 | | 2021-11-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhage intracranial (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 6836 | click or scan EU-EC-10010777807 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6837 | click or scan EU-EC-10010777795 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6838 | click or scan EU-EC-10010777298 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1{DF} - Unknown]) |
| 6839 | click or scan EU-EC-10010776840 | | 2021-11-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Drug interaction (1d - Fatal - **Results in Death**), Muscular weakness (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myopathy (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Poisoning (1d - Fatal - **Results in Death**), Polyneuropathy (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (6d - Fatal - **Results in Death**), Spinal stenosis (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), [GABAPENTIN] (I - Pain - n/a - [n/a - 300mg - Oral]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (I - Pain - n/a - [n/a - n/a - n/a]) |
| 6840 | click or scan EU-EC-10010776813 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Oropharyngeal pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6841 | click or scan EU-EC-10010776698 | | 2021-11-26 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6842 | click or scan EU-EC-10010776564 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (4mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (5mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (5mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (5mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Orthopnoea (3mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6843 | click or scan EU-EC-10010776555 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6844 | click or scan EU-EC-10010776395 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6845 | click or scan EU-EC-10010776379 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Faeces discoloured (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematemesis (n/a - Unknown - Other Medically Important Condition), Shock haemorrhagic (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6846 | click or scan EU-EC-10010776228 | | 2021-11-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 6847 | click or scan EU-EC-10010776216 | | 2021-11-26 | Healthcare Professional | EEA | 18-64 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]), [ENOXAPARIN] (I - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6848 | click or scan EU-EC-10010776145 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6849 | click or scan EU-EC-10010776052 | | 2021-11-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), [INFLUENZA VIRUS] (S - Influenza immunisation - Not applicable - [1 d - 1 {DF} - Unknown]) |
| 6850 | click or scan EU-EC-10010775846 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (2 wk - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (2 wk - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - 1 mL - Intramuscular]) |
| 6851 | click or scan EU-EC-10010775639 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Illness (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6852 | click or scan EU-EC-10010775617 | | 2021-11-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6853 | click or scan EU-EC-10010775605 | | 2021-11-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6854 | click or scan EU-EC-10010775477 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6855 | click or scan EU-EC-10010775469 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6856 | click or scan EU-EC-10010775298 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6857 | click or scan EU-EC-10010774887 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6858 | click or scan EU-EC-10010774664 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6859 | click or scan EU-EC-10010774546 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6860 | click or scan EU-EC-10010774157 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6861 | click or scan EU-EC-10010774017 | | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6862 | click or scan EU-EC-10010773883 | | 2021-11-26 | Non Healthcare Professional | EEA | Not Specified | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 6863 | click or scan EU-EC-10010773845 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6864 | click or scan EU-EC-10010773624 | | 2021-11-26 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6865 | click or scan EU-EC-10010773553 | | 2021-11-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 6866 | click or scan EU-EC-10010773544 | | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6867 | click or scan EU-EC-10010773113 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6868 | click or scan EU-EC-10010773021 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6869 | click or scan EU-EC-10010772887 | | 2021-11-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 6870 | click or scan EU-EC-10010772346 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6871 | click or scan EU-EC-10010772143 | | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6872 | click or scan EU-EC-10010772073 | | 2021-11-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 6873 | click or scan EU-EC-10010771988 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6874 | click or scan EU-EC-10010771953 | | 2021-11-26 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Microangiopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (0d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 6875 | click or scan EU-EC-10010771925 | | 2021-11-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Neoplasm progression (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 6876 | click or scan EU-EC-10010771913 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6877 | click or scan EU-EC-10010771888 | | 2021-11-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Myocardial ischaemia (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 6878 | click or scan EU-EC-10010771824 | | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6879 | click or scan EU-EC-10010771821 |  | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6880 | click or scan EU-EC-10010771800 |  | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Compartment syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematoma muscle (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heparin-induced thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - 1{DF} - n/a]), [HEPARIN, HEPARIN SODIUM] (S - n/a - Drug withdrawn - [3d - n/a - n/a]) |
| 6881 | click or scan EU-EC-10010771657 |  | 2021-11-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 6882 | click or scan EU-EC-10010771648 |  | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6883 | click or scan EU-EC-10010771427 |  | 2021-11-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 6884 | click or scan EU-EC-10010771424 |  | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6885 | click or scan EU-EC-10010771343 |  | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Blood glucose decreased (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neuroleptic malignant syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6886 | click or scan EU-EC-10010771046 |  | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6887 | click or scan EU-EC-10010771031 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6888 | click or scan EU-EC-10010770988 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6889 | click or scan EU-EC-10010770987 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Oedema (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6890 | click or scan EU-EC-10010770918 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Rash (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6891 | click or scan EU-EC-10010770914 | | 2021-11-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Asymptomatic COVID-19 (n/a - Recovered/Resolved - ), COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 6892 | click or scan EU-EC-10010770869 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6893 | click or scan EU-EC-10010770772 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6894 | click or scan EU-EC-10010770761 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6895 | click or scan EU-EC-10010770755 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Unknown - Other Medically Important Condition), Haematuria (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6896 | click or scan EU-EC-10010770750 | | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nasal congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6897 | click or scan EU-EC-10010770715 | | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypomagnesaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic function test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6898 | click or scan EU-EC-10010770662 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6899 | click or scan EU-EC-10010770660 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral microhaemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hydrocephalus (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Monocytosis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neutrophilia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Papilloedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pupil fixed (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition)... | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| 6900 | click or scan EU-EC-10010770633 | | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6901 | click or scan EU-EC-10010770632 | | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **6902** | click or scan EU-EC-10010770296 |  | 2021-11-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **6903** | click or scan EU-EC-10010770220 |  | 2021-11-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6904** | click or scan EU-EC-10010770147 |  | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypersensitivity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **6905** | click or scan EU-EC-10010770101 |  | 2021-11-26 | Healthcare Professional | EEA | 18-64 Years | Male | Decreased activity (n/a - Fatal - **Results in Death**), Hyporeflexia (n/a - Fatal - **Results in Death**), Sopor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [CLOZAPINE] (S - Depression - Dose not changed - [n/a - 300mg - Oral]), [METFORMIN HYDROCHLORIDE] (S - Diabetes mellitus - n/a - [n/a - 1000mg - Oral]), [SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE] (S - n/a - Dose not changed - [n/a - 1500mg - Oral]) |
| **6906** | click or scan EU-EC-10010767894 |  | 2021-11-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **6907** | click or scan EU-EC-10010768658 |  | 2021-11-25 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **6908** | click or scan EU-EC-10010768606 |  | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6909** | click or scan EU-EC-10010768583 |  | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deafness (n/a - Fatal - **Results in Death**, Disabling), Death (n/a - Fatal - **Results in Death**, Disabling), Dizziness (n/a - Fatal - **Results in Death**, Disabling), Hepatic failure (n/a - Fatal - **Results in Death**, Disabling), Laboratory test (n/a - Fatal - **Results in Death**, Disabling), Renal failure (n/a - Fatal - **Results in Death**, Disabling), Vertigo (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6910** | click or scan EU-EC-10010768480 |  | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6911** | click or scan EU-EC-10010768418 |  | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6912 | click or scan EU-EC-10010768364 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bradycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6913 | click or scan EU-EC-10010767943 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6914 | click or scan EU-EC-10010767860 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6915 | click or scan EU-EC-10010767810 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6916 | click or scan EU-EC-10010767628 | | 2021-11-25 | Healthcare Professional | EEA | Not Specified | Not Specified | Foetal disorder (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Recovered/Resolved - **Results in Death**, Congenital Anomaly), Foetal growth restriction (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| 6917 | click or scan EU-EC-10010767438 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6918 | click or scan EU-EC-10010767214 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6919 | click or scan EU-EC-10010767181 | | 2021-11-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - ), Tachycardia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6920 | click or scan EU-EC-10010767169 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6921 | click or scan EU-EC-10010766992 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6922 | click or scan EU-EC-10010766973 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 6923 | click or scan EU-EC-10010766899 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6924 | click or scan EU-EC-10010766789 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Amnesia (132d - Fatal - **Results in Death**), Balance disorder (132d - Fatal - **Results in Death**), Blood test abnormal (132d - Fatal - **Results in Death**), Death (132d - Fatal - **Results in Death**), Fatigue (132d - Fatal - **Results in Death**), Feeling abnormal (132d - Fatal - **Results in Death**), Fibrin D dimer increased (132d - Fatal - **Results in Death**), Glioblastoma (132d - Fatal - **Results in Death**), Headache (132d - Fatal - **Results in Death**), Magnetic resonance imaging head abnormal (132d - Fatal - **Results in Death**), Procedural complication (132d - Fatal - **Results in Death**), Pyrexia (132d - Fatal - **Results in Death**), Tumour excision (132d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6925 | click or scan EU-EC-10010766788 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6926 | click or scan EU-EC-10010766736 | | 2021-11-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6927 | click or scan EU-EC-10010766616 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6928 | click or scan EU-EC-10010766608 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6929 | click or scan EU-EC-10010766329 | | 2021-11-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (1wk - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hallucination (n/a - Fatal - **Results in Death**, Disabling), Headache (n/a - Fatal - **Results in Death**, Disabling), Hypertension (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 6930 | click or scan EU-EC-10010766315 | | 2021-11-25 | Healthcare Professional | EEA | 18-64 Years | Male | Arterial thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Balance disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Impaired self-care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Indifference (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6931 | click or scan EU-EC-10010765321 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6932 | click or scan EU-EC-10010765302 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6933 | click or scan EU-EC-10010765300 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6934 | click or scan EU-EC-10010765150 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6935 | click or scan EU-EC-10010765089 | | 2021-11-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Physical deconditioning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6936 | click or scan EU-EC-10010765064 | | 2021-11-25 | Healthcare Professional | EEA | Not Specified | Male | COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6937 | click or scan EU-EC-10010765000 | | 2021-11-25 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 6938 | click or scan EU-EC-10010764978 | | 2021-11-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **6939** | click or scan EU-EC-10010764948 |  | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Craniocerebral injury (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lacunar infarction (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nerve block (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rib fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6940** | click or scan EU-EC-10010764857 |  | 2021-11-25 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **6941** | click or scan EU-EC-10010764842 |  | 2021-11-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Lymphoma (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **6942** | click or scan EU-EC-10010764808 |  | 2021-11-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - .3mL - Intramuscular]) |
| **6943** | click or scan EU-EC-10010764690 |  | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6944** | click or scan EU-EC-10010764278 |  | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anuria (n/a - Unknown - Other Medically Important Condition), Apnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Insomnia (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6945** | click or scan EU-EC-10010764265 |  | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pancreatic cyst (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **6946** | click or scan EU-EC-10010764178 |  | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **6947** | click or scan EU-EC-10010764151 |  | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6948 | click or scan EU-EC-10010763403 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6949 | click or scan EU-EC-10010763273 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Communication disorder (n/a - Unknown - ), Glossoptosis (n/a - Unknown - ), Hypokinesia (n/a - Unknown - ), Hypophagia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Snoring (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6950 | click or scan EU-EC-10010763050 | | 2021-11-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 6951 | click or scan EU-EC-10010763013 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood gases (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomyopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Extubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory tract haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory tract inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6952 | click or scan EU-EC-10010762491 | | 2021-11-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6953 | click or scan EU-EC-10010762395 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6954 | click or scan EU-EC-10010762381 | | 2021-11-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 6955 | click or scan EU-EC-10010762101 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6956 | click or scan EU-EC-10010761772 |  | 2021-11-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral artery embolism (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Chills (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain in extremity (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Stroke in evolution (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombosis (n/a - Recovered/Resolved With Sequelae - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 6957 | click or scan EU-EC-10010761479 |  | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6958 | click or scan EU-EC-10010761405 |  | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6959 | click or scan EU-EC-10010761333 |  | 2021-11-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6960 | click or scan EU-EC-10010761326 |  | 2021-11-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 6961 | click or scan EU-EC-10010761262 |  | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 6962 | click or scan EU-EC-10010760797 |  | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Activated partial thromboplastin time prolonged (n/a - Fatal - **Results in Death**), Alanine aminotransferase increased (n/a - Fatal - **Results in Death**), Anion gap increased (n/a - Fatal - **Results in Death**), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**), Blood albumin normal (n/a - Fatal - **Results in Death**), Blood alkaline phosphatase normal (n/a - Fatal - **Results in Death**), Blood bicarbonate decreased (n/a - Fatal - **Results in Death**), Blood bilirubin normal (n/a - Fatal - **Results in Death**), Blood calcium decreased (n/a - Fatal - **Results in Death**), Blood chloride normal (n/a - Fatal - **Results in Death**), Blood creatine phosphokinase normal (n/a - Fatal - **Results in Death**), Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood glucose normal (n/a - Fatal - **Results in Death**), Blood lactic acid (n/a - Fatal - **Results in Death**), Blood magnesium increased (n/a - Fatal - **Results in Death**), Blood osmolarity normal (n/a - Fatal - **Results in Death**), Blood pH decreased (n/a - Fatal - **Results in Death**), Blood phosphorus increased (n/a - Fatal - **Results in Death**), Blood potassium normal (n/a - Fatal - **Results in Death**), Blood sodium normal (n/a - Fatal - **Results in Death**), Blood urea normal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Haematocrit normal (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Laboratory test (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Mean cell haemoglobin concentration decreased (n/a - Fatal - **Results in Death**), Mean cell haemoglobin normal (n/a - Fatal - **Results in Death**), Mean cell volume increased (n/a - Fatal - **Results in Death**), N-terminal prohormone brain natriuretic peptide increased (n/a - Fatal - **Results in Death**), PCO2 increased (n/a - Fatal - **Results in Death**), PO2 increased (n/a - Fatal - **Results in Death**), Platelet count normal (n/a - Fatal - **Results in Death**), Protein total decreased (n/a - Fatal - **Results in Death**), Red blood cell count decreased (n/a - Fatal - **Results in Death**), Troponin I increased (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), White blood cell count normal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6963 | click or scan EU-EC-10010760727 |  | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6964 | click or scan EU-EC-10010760620 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 6965 | click or scan EU-EC-10010760566 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Laboratory test (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S- Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 6966 | click or scan EU-EC-10010760327 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 6967 | click or scan EU-EC-10010760068 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S- Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 6968 | click or scan EU-EC-10010759299 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6969 | click or scan EU-EC-10010759233 | | 2021-11-25 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6970 | click or scan EU-EC-10010758789 | | 2021-11-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6971 | click or scan EU-EC-10010758755 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acinetobacter sepsis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Autonomic nervous system imbalance (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral atrophy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Exposure keratitis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Infective keratitis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory acidosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Upper gastrointestinal haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 6972 | click or scan EU-EC-10010758540 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6973 | click or scan EU-EC-10010758490 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6974 | click or scan EU-EC-10010758400 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6975 | click or scan EU-EC-10010758342 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Surgery (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6976 | click or scan EU-EC-10010757990 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypertension (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 6977 | click or scan EU-EC-10010757979 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6978 | click or scan EU-EC-10010757914 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Femur fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hip fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intramedullary rod insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6979 | click or scan EU-EC-10010757788 | | 2021-11-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6980 | click or scan EU-EC-10010757719 | | 2021-11-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Tenderness (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Ultrasound Doppler abnormal (n/a - Fatal - **Results in Death**), Walking aid user (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6981 | click or scan EU-EC-10010757476 | | 2021-11-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6982 | click or scan EU-EC-10010757287 | | 2021-11-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 6983 | click or scan EU-EC-10010756001 | | 2021-11-25 | Healthcare Professional | EEA | 65-85 Years | Male | Infection (13d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| 6984 | click or scan EU-EC-10010755996 | | 2021-11-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (25d - Fatal - **Results in Death**), Chest pain (25d - Fatal - **Results in Death**), Cough (25d - Fatal - **Results in Death**), Diarrhoea (25d - Fatal - **Results in Death**), Dyspnoea (25d - Fatal - **Results in Death**), Extrasystoles (25d - Fatal - **Results in Death**), Hyperhidrosis (25d - Fatal - **Results in Death**), Oxygen saturation decreased (25d - Fatal - **Results in Death**), Rales (25d - Fatal - **Results in Death**), Weight decreased (25d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 6985 | click or scan EU-EC-10010755995 | | 2021-11-25 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (15d - Fatal - **Results in Death**), Interstitial lung disease (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 6986 | click or scan EU-EC-10010755383 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 6987 | click or scan EU-EC-10010755366 | | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6988 | click or scan EU-EC-10010754784 | | 2021-11-24 | Healthcare Professional | EEA | Not Specified | Not Specified | Foetal exposure during pregnancy (n/a - Recovered/Resolved - **Results in Death**, Congenital Anomaly), Foetal malformation (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| 6989 | click or scan EU-EC-10010754356 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 6990 | click or scan EU-EC-10010754356 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 6991 | click or scan EU-EC-10010754102 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Balance disorder (n/a - Fatal - **Results in Death**), Cast application (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Humerus fracture (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Upper limb fracture (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 6992 | click or scan EU-EC-10010753965 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 6993 | click or scan EU-EC-10010753861 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthropathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Head injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Walking aid user (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheelchair user (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 6994 | click or scan EU-EC-10010753398 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 6995 | click or scan EU-EC-10010753041 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Life Threatening), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **6996** | click or scan EU-EC-10010752928 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **6997** | click or scan EU-EC-10010752686 | | 2021-11-24 | Healthcare Professional | EEA | Not Specified | Not Specified | Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**), Oligohydramnios (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transplacental]) |
| **6998** | click or scan EU-EC-10010752595 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **6999** | click or scan EU-EC-10010752581 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **7000** | click or scan EU-EC-10010752548 | | 2021-11-24 | Healthcare Professional | EEA | 18-64 Years | Female | Condition aggravated (1d - Fatal - **Results in Death**), Hypertrophic cardiomyopathy (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [25d - 2 {DF} - Intramuscular]) |
| **7001** | click or scan EU-EC-10010752522 | | 2021-11-24 | Healthcare Professional | EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Prion disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **7002** | click or scan EU-EC-10010752430 | | 2021-11-24 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **7003** | click or scan EU-EC-10010752229 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Myalgia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7004** | click or scan EU-EC-10010752225 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7005** | click or scan EU-EC-10010752223 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous thrombosis (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7006** | click or scan EU-EC-10010751946 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Life support (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7007** | click or scan EU-EC-10010751921 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ear haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Psychomotor hyperactivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7008** | click or scan EU-EC-10010751916 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **7009** | click or scan EU-EC-10010751818 | | 2021-11-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Motor dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **7010** | click or scan EU-EC-10010751703 | | 2021-11-24 | Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - ), Meningism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7011** | click or scan EU-EC-10010751638 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7012** | click or scan EU-EC-10010751634 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7013** | click or scan EU-EC-10010751597 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7014** | click or scan EU-EC-10010751576 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea at rest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7015** | click or scan EU-EC-10010750837 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Syncope (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **7016** | click or scan EU-EC-10010750778 |  | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiogenic shock (7d - Fatal - **Results in Death**), Thrombosis (7d - Fatal - **Results in Death**), Ventricular extrasystoles (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7017** | click or scan EU-EC-10010750549 |  | 2021-11-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dependence on respirator (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ill-defined disorder (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **7018** | click or scan EU-EC-10010750133 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7019** | click or scan EU-EC-10010750115 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7020** | click or scan EU-EC-10010750110 |  | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Generalised oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oliguria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Orthopnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7021** | click or scan EU-EC-10010749394 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7022** | click or scan EU-EC-10010748827 |  | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain lower (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Angiogram (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Echocardiogram abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ultrasound scan abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **7023** | click or scan EU-EC-10010748646 |  | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7024 | click or scan EU-EC-10010748581 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal rigidity (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7025 | click or scan EU-EC-10010748455 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anticoagulant therapy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Jugular vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subclavian vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7026 | click or scan EU-EC-10010748331 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atelectasis (15d - Fatal - **Results in Death**), COVID-19 (15d - Fatal - **Results in Death**), Chest X-ray abnormal (15d - Fatal - **Results in Death**), Cough (15d - Fatal - **Results in Death**), Death (15d - Fatal - **Results in Death**, Other Medically Important Condition), Effusion (15d - Fatal - **Results in Death**), Generalised oedema (15d - Fatal - **Results in Death**), Lung infiltration (15d - Fatal - **Results in Death**), Lung opacity (15d - Fatal - **Results in Death**), Malaise (15d - Fatal - **Results in Death**), Pneumonia (15d - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (15d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7027 | click or scan EU-EC-10010748305 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7028 | click or scan EU-EC-10010747649 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 7029 | click or scan EU-EC-10010747618 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7030 | click or scan EU-EC-10010747606 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Female | Malaise (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7031 | click or scan EU-EC-10010747573 | | 2021-11-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Intestinal infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7032 | click or scan EU-EC-10010747571 | | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7033 | click or scan EU-EC-10010747567 |  | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7034 | click or scan EU-EC-10010747505 |  | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7035 | click or scan EU-EC-10010747062 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening), Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Life Threatening), Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Recovering/Resolving - Life Threatening), Pruritus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Recovering/Resolving - Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7036 | click or scan EU-EC-10010746929 |  | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7037 | click or scan EU-EC-10010746807 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7038 | click or scan EU-EC-10010746805 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Nephropathy (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7039 | click or scan EU-EC-10010746720 |  | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 7040 | click or scan EU-EC-10010746606 |  | 2021-11-24 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 7041 | click or scan EU-EC-10010746598 |  | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 7042 | click or scan EU-EC-10010746343 |  | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disorganised speech (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia aspiration (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7043 | click or scan EU-EC-10010746208 |  | 2021-11-24 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 7044 | click or scan EU-EC-10010746185 |  | 2021-11-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Idiopathic pulmonary fibrosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7045 | click or scan EU-EC-10010746039 |  | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7046 | click or scan EU-EC-10010743776 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7047 | click or scan EU-EC-10010743710 |  | 2021-11-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7048 | click or scan EU-EC-10010743501 |  | 2021-11-24 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7049 | click or scan EU-EC-10010743061 |  | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7050 | click or scan EU-EC-10010743001 |  | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7051 | click or scan EU-EC-10010742903 |  | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**), Chemotherapy (4d - Fatal - **Results in Death**), Cough (4d - Fatal - **Results in Death**), Death (4d - Fatal - **Results in Death**, Other Medically Important Condition), Lung cancer metastatic (4d - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7052 | click or scan EU-EC-10010742279 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Autopsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lumbar puncture (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7053 | click or scan EU-EC-10010742271 | | 2021-11-24 | Healthcare Professional | Non EEA | Not Specified | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7054 | click or scan EU-EC-10010742033 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood albumin decreased (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Blood urea increased (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Coma (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Drainage (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea exertional (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Haematocrit decreased (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Haemoglobin decreased (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Loss of consciousness (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mechanical ventilation (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Monocyte count increased (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Protein total decreased (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pulmonary oedema (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Red blood cell count decreased (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Tooth extraction (6mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 7055 | click or scan EU-EC-10010741546 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7056 | click or scan EU-EC-10010741329 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7057 | click or scan EU-EC-10010741328 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7058 | click or scan EU-EC-10010741309 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Cranial nerve disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (24d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mitral valve incompetence (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (28d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (28d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7059 | click or scan EU-EC-10010741218 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7060** | click or scan EU-EC-10010741212 | | 2021-11-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7061** | click or scan EU-EC-10010741209 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neck pain (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7062** | click or scan EU-EC-10010741196 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7063** | click or scan EU-EC-10010741174 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (18d - Fatal - **Results in Death**), SARS-CoV-2 test positive (18d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7064** | click or scan EU-EC-10010741165 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccine breakthrough infection (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7065** | click or scan EU-EC-10010741163 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic valve replacement (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac pacemaker insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7066** | click or scan EU-EC-10010741026 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **7067** | click or scan EU-EC-10010741023 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**), Positive airway pressure therapy (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7068** | click or scan EU-EC-10010741021 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Respiratory tract congestion (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7069** | click or scan EU-EC-10010740982 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7070 | click or scan EU-EC-10010740958 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pollakiuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7071 | click or scan EU-EC-10010740790 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7072 | click or scan EU-EC-10010740745 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7073 | click or scan EU-EC-10010740729 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7074 | click or scan EU-EC-10010740269 | | 2021-11-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7075 | click or scan EU-EC-10010740267 | | 2021-11-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7076 | click or scan EU-EC-10010740000 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (10d - Fatal - **Results in Death**), COVID-19 pneumonia (10d - Fatal - **Results in Death**), Diarrhoea (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), SARS-CoV-2 test positive (10d - Fatal - **Results in Death**), Vaccination failure (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 7077 | click or scan EU-EC-10010739842 | | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7078** | click or scan EU-EC-10010739705 | | 2021-11-24 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (82d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7079** | click or scan EU-EC-10010739692 | | 2021-11-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular disorder (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7080** | click or scan EU-EC-10010739545 | | 2021-11-24 | Healthcare Professional | EEA | More than 85 Years | Male | Coma (3d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Hypernatraemia (3d - Fatal - **Results in Death**), Leukopenia (3d - Fatal - **Results in Death**), Lymphopenia (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Respiratory acidosis (3d - Fatal - **Results in Death**), SARS-CoV-2 test positive (3d - Fatal - **Results in Death**), Vaccination failure (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **7081** | click or scan EU-EC-10010734190 | | 2021-11-23 | Healthcare Professional | EEA | 18-64 Years | Female | Aplastic anaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **7082** | click or scan EU-EC-10010731581 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7083** | click or scan EU-EC-10010731558 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7084** | click or scan EU-EC-10010731456 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7085** | click or scan EU-EC-10010730820 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Cardiomyopathy (170d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Cough (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Erythema (n/a - Unknown - ), Eye pruritus (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hypoaesthesia (n/a - Unknown - ), Lacrimation increased (n/a - Unknown - ), Myocarditis (23d - Fatal - **Results in Death**, Other Medically Important Condition), Ocular hyperaemia (n/a - Unknown - ), Paraesthesia (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Pruritus (n/a - Unknown - ), Rash (n/a - Unknown - ), Skin discolouration (n/a - Unknown - ), Skin exfoliation (n/a - Unknown - ), Swelling face (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7086 | click or scan EU-EC-10010730099 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Activated partial thromboplastin time shortened (n/a - Unknown - ), Basophil count decreased (n/a - Unknown - ), Blood bilirubin increased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood fibrinogen increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), Brain natriuretic peptide increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea exertional (n/a - Not Recovered/Not Resolved - ), Fibrin D dimer increased (n/a - Unknown - ), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Interstitial lung disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung adenocarcinoma (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Orthopnoea (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Red blood cell count decreased (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ), Troponin I increased (n/a - Unknown - ), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7087 | click or scan EU-EC-10010729670 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7088 | click or scan EU-EC-10010729305 | | 2021-11-23 | Healthcare Professional | EEA | 65-85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7089 | click or scan EU-EC-10010729294 | | 2021-11-23 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7090 | click or scan EU-EC-10010729283 | | 2021-11-23 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7091 | click or scan EU-EC-10010728990 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7092 | click or scan EU-EC-10010728565 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7093 | click or scan EU-EC-10010728560 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7094 | click or scan EU-EC-10010728383 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Autoimmune haemolytic anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Haemolytic anaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metastases to peritoneum (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Metastatic neoplasm (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Plasma cell myeloma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic microangiopathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7095 | click or scan EU-EC-10010727982 | | 2021-11-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), General physical health deterioration (7d - Fatal - **Results in Death**), Pneumonia (5d - Fatal - **Results in Death**), Pyrexia (6d - Fatal - **Results in Death**), Rales (6d - Fatal - **Results in Death**), Urinary tract infection (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7096 | click or scan EU-EC-10010727803 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7097 | click or scan EU-EC-10010727764 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7098 | click or scan EU-EC-10010727757 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7099 | click or scan EU-EC-10010727453 | | 2021-11-23 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [20d - 2 {DF} - Intramuscular]) |
| 7100 | click or scan EU-EC-10010727366 | | 2021-11-23 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2 {DF} - Intramuscular]) |
| 7101 | click or scan EU-EC-10010727261 | | 2021-11-23 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1 {DF} - Intramuscular]) |
| 7102 | click or scan EU-EC-10010727237 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory distress (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7103 | click or scan EU-EC-10010727235 | | 2021-11-23 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [77d - 2 {DF} - Intramuscular]) |
| 7104 | click or scan EU-EC-10010727121 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7105 | click or scan EU-EC-10010727019 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7106 | click or scan EU-EC-10010726996 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7107 | click or scan EU-EC-10010726954 | | 2021-11-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Bone pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperglycaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7108 | click or scan EU-EC-10010726830 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7109 | click or scan EU-EC-10010726324 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Productive cough (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7110 | click or scan EU-EC-10010726263 | | 2021-11-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7111 | click or scan EU-EC-10010726192 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7112 | click or scan EU-EC-10010726185 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysuria (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 7113 | click or scan EU-EC-10010725902 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Alanine aminotransferase increased (n/a - Unknown - ), Aspartate aminotransferase increased (n/a - Unknown - ), Blood creatine phosphokinase MB increased (n/a - Unknown - Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - ), Coronary artery stenosis (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema peripheral (n/a - Unknown - ), Pallor (n/a - Unknown - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7114 | click or scan EU-EC-10010725897 |  | 2021-11-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Medical induction of coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7115 | click or scan EU-EC-10010725863 |  | 2021-11-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7116 | click or scan EU-EC-10010725604 |  | 2021-11-23 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7117 | click or scan EU-EC-10010725334 |  | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7118 | click or scan EU-EC-10010725317 |  | 2021-11-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7119 | click or scan EU-EC-10010725165 |  | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7120 | click or scan EU-EC-10010725160 |  | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7121 | click or scan EU-EC-10010724711 |  | 2021-11-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bacterial sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7122 | click or scan EU-EC-10010724703 |  | 2021-11-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7123 | click or scan EU-EC-10010724701 |  | 2021-11-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7124 | click or scan EU-EC-10010724698 | | 2021-11-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7125 | click or scan EU-EC-10010724697 | | 2021-11-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | B-cell lymphoma (n/a - Fatal - **Results in Death**), Testis cancer (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7126 | click or scan EU-EC-10010724671 | | 2021-11-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7127 | click or scan EU-EC-10010724460 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7128 | click or scan EU-EC-10010724451 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7129 | click or scan EU-EC-10010724449 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Quadriparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7130 | click or scan EU-EC-10010724242 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7131 | click or scan EU-EC-10010724111 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7132 | click or scan EU-EC-10010724040 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7133 | click or scan EU-EC-10010723889 | | 2021-11-23 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ileus (2d - Fatal - **Results in Death**), Mesenteric artery thrombosis (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7134 | click or scan EU-EC-10010723620 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Myalgia (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7135 | click or scan EU-EC-10010723454 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7136 | click or scan EU-EC-10010722769 | | 2021-11-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7137 | click or scan EU-EC-10010722755 | | 2021-11-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7138 | click or scan EU-EC-10010722741 | | 2021-11-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7139 | click or scan EU-EC-10010722706 | | 2021-11-23 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7140 | click or scan EU-EC-10010722583 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7141 | click or scan EU-EC-10010722512 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7142 | click or scan EU-EC-10010722453 | | 2021-11-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 7143 | click or scan EU-EC-10010722351 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7144 | click or scan EU-EC-10010721979 | | 2021-11-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (62d - Fatal - **Results in Death**), Headache (62d - Fatal - **Results in Death**), Neoplasm (62d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7145 | click or scan EU-EC-10010721874 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Skin discolouration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 7146 | click or scan EU-EC-10010721718 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myalgia intercostal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7147 | click or scan EU-EC-10010721657 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7148 | click or scan EU-EC-10010721647 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7149 | click or scan EU-EC-10010721633 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7150 | click or scan EU-EC-10010721512 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7151 | click or scan EU-EC-10010721511 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 7152 | click or scan EU-EC-10010721452 | | 2021-11-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 7153 | click or scan EU-EC-10010721383 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7154 | click or scan EU-EC-10010720986 | | 2021-11-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pollakiuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7155 | click or scan EU-EC-10010720852 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7156 | click or scan EU-EC-10010720824 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7157 | click or scan EU-EC-10010720716 | | 2021-11-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7158 | click or scan EU-EC-10010720658 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem embolism (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7159 | click or scan EU-EC-10010720574 | | 2021-11-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7160 | click or scan EU-EC-10010720565 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7161 | click or scan EU-EC-10010720023 | | 2021-11-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 7162 | click or scan EU-EC-10010719615 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ), Multisystem inflammatory syndrome in adults (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7163 | click or scan EU-EC-10010719614 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7164 | click or scan EU-EC-10010719613 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Unknown - Other Medically Important Condition), International normalised ratio increased (n/a - Unknown - Other Medically Important Condition), Troponin I increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7165 | click or scan EU-EC-10010719347 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7166 | click or scan EU-EC-10010719333 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7167 | click or scan EU-EC-10010719268 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7168 | click or scan EU-EC-10010719213 | | 2021-11-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cognitive disorder (68d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 7169 | click or scan EU-EC-10010718905 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Oxygen saturation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7170 | click or scan EU-EC-10010718655 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (9d - Fatal - **Results in Death**), Headache (8d - Fatal - **Results in Death**), Pyrexia (9d - Fatal - **Results in Death**), Vaccination site pain (n/a - Recovering/Resolving - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7171 | click or scan EU-EC-10010718621 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7172 | click or scan EU-EC-10010718521 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7173 | click or scan EU-EC-10010718473 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anosmia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7174 | click or scan EU-EC-10010718384 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7175 | click or scan EU-EC-10010718381 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7176 | click or scan EU-EC-10010718370 | | 2021-11-22 | Healthcare Professional | EEA | 18-64 Years | Male | Adrenal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Bile duct stenosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Electrolyte imbalance (n/a - Unknown - Caused/Prolonged Hospitalisation), Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemangioma of liver (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic haemangioma rupture (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7177 | click or scan EU-EC-10010718365 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7178 | click or scan EU-EC-10010718327 | | 2021-11-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (0d - Fatal - **Results in Death**), Exposure to vaccinated person (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7179 | click or scan EU-EC-10010718292 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7180 | click or scan EU-EC-10010717938 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7181 | click or scan EU-EC-10010717266 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7182 | click or scan EU-EC-10010717230 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (1d - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7183 | click or scan EU-EC-10010717151 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7184 | click or scan EU-EC-10010717140 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7185 | click or scan EU-EC-10010717108 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7186 | click or scan EU-EC-10010717086 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7187 | click or scan EU-EC-10010717006 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7188 | click or scan EU-EC-10010716998 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7189 | click or scan EU-EC-10010716883 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7190 | click or scan EU-EC-10010716858 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7191 | click or scan EU-EC-10010716741 | | 2021-11-22 | Healthcare Professional | Non EEA | Not Specified | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Miller Fisher syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7192 | click or scan EU-EC-10010716685 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7193 | click or scan EU-EC-10010716679 | | 2021-11-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 7194 | click or scan EU-EC-10010716565 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral disorder (n/a - Fatal - **Results in Death**), Hydrocephalus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7195 | click or scan EU-EC-10010716517 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7196 | click or scan EU-EC-10010716418 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - ), Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7197 | click or scan EU-EC-10010716412 | | 2021-11-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral disorder (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Delusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Hallucination, visual (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of control of legs (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7198 | click or scan EU-EC-10010716282 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diabetes mellitus (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7199 | click or scan EU-EC-10010715942 | | 2021-11-22 | Healthcare Professional | EEA | Not Specified | Male | Foetal death (n/a - Fatal - **Results in Death**), Hydrocephalus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| 7200 | click or scan EU-EC-10010715883 | | 2021-11-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7201 | click or scan EU-EC-10010715305 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Coronary artery occlusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7202 | click or scan EU-EC-10010715288 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atherosclerotic plaque rupture (n/a - Unknown - Other Medically Important Condition), Coronary artery occlusion (n/a - Unknown - Other Medically Important Condition), Coronary artery thrombosis (n/a - Unknown - Other Medically Important Condition), Myocardial fibrosis (n/a - Unknown - Other Medically Important Condition), Myocardial necrosis (n/a - Unknown - Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7203 | click or scan EU-EC-10010715145 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7204 | click or scan EU-EC-10010715078 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7205 | click or scan EU-EC-10010715011 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Metabolic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Septic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7206 | click or scan EU-EC-10010715010 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Face oedema (7d - Recovered/Resolved - Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema peripheral (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7207 | click or scan EU-EC-10010714226 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7208 | click or scan EU-EC-10010714169 | | 2021-11-22 | Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7209 | click or scan EU-EC-10010714118 | | 2021-11-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7210 | click or scan EU-EC-10010713021 | | 2021-11-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7211 | click or scan EU-EC-10010712993 | | 2021-11-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abortion (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Death (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7212 | click or scan EU-EC-10010712988 | | 2021-11-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7213 | click or scan EU-EC-10010712980 | | 2021-11-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7214 | click or scan EU-EC-10010712973 | | 2021-11-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure increased (n/a - Not Recovered/Not Resolved - ), Chest discomfort (n/a - Not Recovered/Not Resolved - ), Influenza (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7215 | click or scan EU-EC-10010712856 | | 2021-11-22 | Non Healthcare Professional | EEA | Not Specified | Male | Infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7216 | click or scan EU-EC-10010712837 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Weight increased (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7217 | click or scan EU-EC-10010712775 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [DONEPEZIL HYDROCHLORIDE] (S - n/a - Unknown - [n/a - n/a - Oral]) |
| 7218 | click or scan EU-EC-10010712773 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7219 | click or scan EU-EC-10010712662 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Ear pain (n/a - Unknown - ), Myocardial rupture (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7220 | click or scan EU-EC-10010712653 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7221 | click or scan EU-EC-10010712647 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - ), Hyperemesis gravidarum (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Unknown - ), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7222 | click or scan EU-EC-10010712611 | | 2021-11-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7223 | click or scan EU-EC-10010712608 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7224 | click or scan EU-EC-10010712596 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulse absent (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7225 | click or scan EU-EC-10010712595 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7226 | click or scan EU-EC-10010712537 | | 2021-11-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7227 | click or scan EU-EC-10010712517 | | 2021-11-22 | Healthcare Professional | EEA | 65-85 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7228 | click or scan EU-EC-10010712349 | | 2021-11-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7229 | click or scan EU-EC-10010712297 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7230 | click or scan EU-EC-10010712295 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7231 | click or scan EU-EC-10010711807 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7232 | click or scan EU-EC-10010711541 |  | 2021-11-22 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Adenocarcinoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung opacity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - ), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Purpura (n/a - Unknown - ), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site inflammation (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Weight decreased (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7233 | click or scan EU-EC-10010711373 |  | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pain in extremity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7234 | click or scan EU-EC-10010711372 |  | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7235 | click or scan EU-EC-10010711321 |  | 2021-11-22 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7236 | click or scan EU-EC-10010711305 |  | 2021-11-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7237 | click or scan EU-EC-10010711251 |  | 2021-11-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7238 | click or scan EU-EC-10010710959 |  | 2021-11-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7239 | click or scan EU-EC-10010710808 |  | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7240 | click or scan EU-EC-10010710752 | | 2021-11-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7241 | click or scan EU-EC-10010710395 | | 2021-11-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7242 | click or scan EU-EC-10010710352 | | 2021-11-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7243 | click or scan EU-EC-10010710329 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7244 | click or scan EU-EC-10010710276 | | 2021-11-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Balance disorder (n/a - Fatal - **Results in Death**), Cognitive disorder (n/a - Fatal - **Results in Death**), Death (9d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**), Large intestinal obstruction (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7245 | click or scan EU-EC-10010710274 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7246 | click or scan EU-EC-10010710261 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7247 | click or scan EU-EC-10010710210 | | 2021-11-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Acute cardiac event (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7248 | click or scan EU-EC-10010710094 | | 2021-11-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**), Endocarditis (n/a - Unknown - ), Guillain-Barre syndrome (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7249 | click or scan EU-EC-10010710073 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7250 | click or scan EU-EC-10010709905 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7251 | click or scan EU-EC-10010709628 | | 2021-11-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 7252 | click or scan EU-EC-10010709069 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Other Medically Important Condition), Autoimmune haemolytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bradycardia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7253 | click or scan EU-EC-10010709025 | | 2021-11-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac dysfunction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7254 | click or scan EU-EC-10010709002 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Vaccination site pain (2d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7255 | click or scan EU-EC-10010708953 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cyanosis (n/a - Unknown - ), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Erythema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Petechiae (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Purpura (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**), White blood cell count decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7256 | click or scan EU-EC-10010708930 | | 2021-11-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7257 | click or scan EU-EC-10010708924 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7258 | click or scan EU-EC-10010708907 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7259 | click or scan EU-EC-10010708506 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7260 | click or scan EU-EC-10010708494 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7261 | click or scan EU-EC-10010708306 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7262 | click or scan EU-EC-10010708164 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7263 | click or scan EU-EC-10010707986 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (15d - Fatal - **Results in Death**), Dyspnoea (15d - Fatal - **Results in Death**), Headache (15d - Fatal - **Results in Death**), Pyrexia (15d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7264 | click or scan EU-EC-10010707562 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7265 | click or scan EU-EC-10010707558 | | 2021-11-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7266 | click or scan EU-EC-10010707537 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine output decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7267** | click or scan EU-EC-10010707515 | | 2021-11-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7268** | click or scan EU-EC-10010707365 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **7269** | click or scan EU-EC-10010707211 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7270** | click or scan EU-EC-10010707177 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **7271** | click or scan EU-EC-10010707135 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7272** | click or scan EU-EC-10010707115 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7273** | click or scan EU-EC-10010707094 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7274** | click or scan EU-EC-10010707049 | | 2021-11-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **7275** | click or scan EU-EC-10010707048 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7276 | click or scan EU-EC-10010706926 | | 2021-11-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Escherichia infection (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Escherichia sepsis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sopor (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Systemic bacterial infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7277 | click or scan EU-EC-10010706804 | | 2021-11-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7278 | click or scan EU-EC-10010705889 | | 2021-11-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7279 | click or scan EU-EC-10010705449 | | 2021-11-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7280 | click or scan EU-EC-10010705447 | | 2021-11-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7281 | click or scan EU-EC-10010704685 | | 2021-11-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 7282 | click or scan EU-EC-10010704684 | | 2021-11-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7283 | click or scan EU-EC-10010704640 | | 2021-11-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiomegaly (n/a - Unknown - ), Constipation (n/a - Unknown - ), Device dislocation (1d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Unknown - ), Faeces soft (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Gastroenteritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Hypervolaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - ), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infusion site erythema (n/a - Unknown - ), Infusion site induration (n/a - Unknown - ), Infusion site pain (n/a - Unknown - ), Infusion site swelling (n/a - Unknown - ), Malaise (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nasal dryness (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen consumption increased (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Rectal haemorrhage (n/a - Unknown - Other Medically Important Condition), Unintentional medical device removal (n/a - Recovered/Resolved - ), Vaccination complication (n/a - Unknown - ), Weight increased (n/a - Unknown - ) | ADEMPAS [RIOCIGUAT] (S - Product used for unknown indication - Not applicable - [n/a - 3mg - Unknown - More in ICSR]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [OXYGEN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]), [TREPROSTINIL, TREPROSTINIL SODIUM] (S - Pulmonary arterial hypertension - Not applicable - [n/a - .024ug/kg - Subcutaneous - More in ICSR]) |
| 7284 | click or scan EU-EC-10010703769 | | 2021-11-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Feeling cold (n/a - Fatal - **Results in Death**), Haematuria (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 7285 | click or scan EU-EC-10010703753 | | 2021-11-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Blood pressure increased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Diverticulitis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7286 | click or scan EU-EC-10010703067 | | 2021-11-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), IMMUNOTHERAPIE (IMMUUNTHERAPIE) [NOT AVAILABLE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 7287 | click or scan EU-EC-10010701499 | | 2021-11-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7288 | click or scan EU-EC-10010702868 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7289 | click or scan EU-EC-10010702750 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 7290 | click or scan EU-EC-10010702339 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (1mo - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7291 | click or scan EU-EC-10010702130 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7292 | click or scan EU-EC-10010701867 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Unknown - Life Threatening), Muscular weakness (n/a - Fatal - **Results in Death**, Life Threatening), Nasal congestion (n/a - Fatal - **Results in Death**, Life Threatening), Oropharyngeal discomfort (n/a - Fatal - **Results in Death**, Life Threatening), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7293 | click or scan EU-EC-10010701727 | | 2021-11-19 | Healthcare Professional | EEA | More than 85 Years | Male | Acute abdomen (2d - Fatal - **Results in Death**), Diarrhoea (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) |
| 7294 | click or scan EU-EC-10010700854 | | 2021-11-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7295 | click or scan EU-EC-10010700805 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7296 | click or scan EU-EC-10010700799 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7297 | click or scan EU-EC-10010700797 | | 2021-11-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7298 | click or scan EU-EC-10010700795 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7299 | click or scan EU-EC-10010700790 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7300 | click or scan EU-EC-10010700766 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac murmur (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pallor (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse abnormal (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7301 | click or scan EU-EC-10010700464 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7302 | click or scan EU-EC-10010700452 |  | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7303 | click or scan EU-EC-10010700242 |  | 2021-11-19 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 7304 | click or scan EU-EC-10010700168 |  | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7305 | click or scan EU-EC-10010700167 |  | 2021-11-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7306 | click or scan EU-EC-10010700050 |  | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7307 | click or scan EU-EC-10010699782 |  | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7308 | click or scan EU-EC-10010699776 |  | 2021-11-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7309 | click or scan EU-EC-10010699714 |  | 2021-11-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dependence on respirator (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7310 | click or scan EU-EC-10010699633 |  | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7311 | click or scan EU-EC-10010699579 |  | 2021-11-19 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7312 | click or scan EU-EC-10010699403 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7313 | click or scan EU-EC-10010698987 | | 2021-11-19 | Non Healthcare Professional | EEA | 18-64 Years | Female | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7314 | click or scan EU-EC-10010698969 | | 2021-11-19 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 7315 | click or scan EU-EC-10010698172 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7316 | click or scan EU-EC-10010698108 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**), Chills (10d - Recovered/Resolved - ), Dyspnoea (10d - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**), Haemoglobin (n/a - Fatal - **Results in Death**), Pyrexia (4320min - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7317 | click or scan EU-EC-10010698049 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7318 | click or scan EU-EC-10010697985 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**), COVID-19 pneumonia (8d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), Hypoxia (10d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 7319 | click or scan EU-EC-10010697874 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7320 | click or scan EU-EC-10010697745 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7321 | click or scan EU-EC-10010697743 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7322 | click or scan EU-EC-10010697603 | | 2021-11-19 | Healthcare Professional | EEA | 18-64 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7323 | click or scan EU-EC-10010697520 | | 2021-11-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7324 | click or scan EU-EC-10010697482 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Influenza like illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7325 | click or scan EU-EC-10010697475 | | 2021-11-19 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7326 | click or scan EU-EC-10010697474 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7327 | click or scan EU-EC-10010697473 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7328 | click or scan EU-EC-10010697444 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (10d - Fatal - **Results in Death**), Asthenia (10d - Fatal - **Results in Death**), Bronchial wall thickening (10d - Fatal - **Results in Death**), COVID-19 (10d - Fatal - **Results in Death**), Chills (10d - Fatal - **Results in Death**), Death (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), Headache (10d - Fatal - **Results in Death**), Hypoxia (10d - Fatal - **Results in Death**), Lung infiltration (10d - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**), SARS-CoV-2 test positive (10d - Fatal - **Results in Death**), Vaccination failure (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7329 | click or scan EU-EC-10010697351 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7330 | click or scan EU-EC-10010697347 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7331 | click or scan EU-EC-10010697345 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7332 | click or scan EU-EC-10010697270 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7333 | click or scan EU-EC-10010697078 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7334 | click or scan EU-EC-10010696967 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), INFLUENZA A VIRUS, A/CAMBODIA/E0826360/2020 (H3N2) - LIKE STRAIN (A/TASMANIA/503/2020, IVR-221), INACTIVATED] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7335 | click or scan EU-EC-10010696812 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7336 | click or scan EU-EC-10010696532 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7337 | click or scan EU-EC-10010696370 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7338 | click or scan EU-EC-10010696235 | | 2021-11-19 | Healthcare Professional | EEA | 18-64 Years | Male | Dysphagia (5d - Fatal - **Results in Death**), Hypotension (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7339 | click or scan EU-EC-10010696129 | | 2021-11-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Encephalitis (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7340 | click or scan EU-EC-10010695619 | | 2021-11-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7341 | click or scan EU-EC-10010695343 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7342 | click or scan EU-EC-10010695233 | | 2021-11-19 | Healthcare Professional | EEA | 18-64 Years | Male | Epilepsy (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [CARBAMAZEPINE] (S - Epilepsy - Dose reduced - [n/a - n/a - n/a]) |
| 7343 | click or scan EU-EC-10010695054 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Injection site swelling (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7344 | click or scan EU-EC-10010694258 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7345 | click or scan EU-EC-10010694249 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Myalgia (1d - Fatal - **Results in Death**), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7346 | click or scan EU-EC-10010693677 | | 2021-11-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pancreatic carcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7347 | click or scan EU-EC-10010693443 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tenderness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7348 | click or scan EU-EC-10010693182 | | 2021-11-19 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7349 | click or scan EU-EC-10010693123 | | 2021-11-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Back pain (13d - Fatal - **Results in Death**, Other Medically Important Condition), Lung neoplasm malignant (13d - Fatal - **Results in Death**, Other Medically Important Condition), Paralysis (13d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7350 | click or scan EU-EC-10010693006 | | 2021-11-19 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7351 | click or scan EU-EC-10010692897 | | 2021-11-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7352 | click or scan EU-EC-10010692723 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7353 | click or scan EU-EC-10010692076 | | 2021-11-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7354 | click or scan EU-EC-10010691453 | | 2021-11-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Intracranial aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7355 | click or scan EU-EC-10010689818 | | 2021-11-18 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (3d - Fatal - **Results in Death**), Condition aggravated (3d - Fatal - **Results in Death**), Infective exacerbation of bronchiectasis (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 7356 | click or scan EU-EC-10010688989 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Reaction to excipient (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7357 | click or scan EU-EC-10010688949 | | 2021-11-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7358 | click or scan EU-EC-10010688644 | | 2021-11-18 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Foetal hypokinesia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental]) |
| 7359 | click or scan EU-EC-10010688387 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Vaccination site pain (n/a - Fatal - **Results in Death**), Vaccination site swelling (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7360 | click or scan EU-EC-10010688107 | | 2021-11-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7361 | click or scan EU-EC-10010687429 | | 2021-11-18 | Healthcare Professional | EEA | More than 85 Years | Male | Haematoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [25d - 1 {DF} - Intramuscular]) |
| 7362 | click or scan EU-EC-10010687372 | | 2021-11-18 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Myalgia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7363 | click or scan EU-EC-10010687352 | | 2021-11-18 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 7364 | click or scan EU-EC-10010687315 | | 2021-11-18 | Healthcare Professional | EEA | 65-85 Years | Male | Anaemia (3mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7365 | click or scan EU-EC-10010687205 | | 2021-11-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7366 | click or scan EU-EC-10010686822 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Echocardiogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7367 | click or scan EU-EC-10010685947 | | 2021-11-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bladder catheter permanent (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Incontinence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 7368 | click or scan EU-EC-10010685761 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Mental status changes (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7369** | click or scan EU-EC-10010685716 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7370** | click or scan EU-EC-10010685683 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7371** | click or scan EU-EC-10010685491 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7372** | click or scan EU-EC-10010685451 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Hepatic function abnormal (29d - Recovered/Resolved - ), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Pneumothorax (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**), Stress cardiomyopathy (n/a - Unknown - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mg - Intramuscular]), [ABEMACICLIB] (S - Breast cancer recurrent - Drug withdrawn - [21d - 200mg - Oral - More in ICSR]), [ANASTROZOLE] (S - Breast cancer recurrent - Drug withdrawn - [42d - 1mg - Oral - More in ICSR]) |
| **7373** | click or scan EU-EC-10010685247 | | 2021-11-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **7374** | click or scan EU-EC-10010684974 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neutrophilia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7375** | click or scan EU-EC-10010684706 | | 2021-11-18 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **7376** | click or scan EU-EC-10010684662 | | 2021-11-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7377 | click or scan EU-EC-10010684461 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7378 | click or scan EU-EC-10010684262 | | 2021-11-18 | Healthcare Professional | EEA | 18-64 Years | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 7379 | click or scan EU-EC-10010684239 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7380 | click or scan EU-EC-10010684094 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7381 | click or scan EU-EC-10010683557 | | 2021-11-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Hypersensitivity (n/a - Fatal - **Results in Death**), Swelling face (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (I - Immunisation - n/a - [n/a - n/a - n/a]), [AMIODARONE HYDROCHLORIDE] (S - n/a - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 7382 | click or scan EU-EC-10010683348 | | 2021-11-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7383 | click or scan EU-EC-10010682873 | | 2021-11-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dry skin (n/a - Unknown - Caused/Prolonged Hospitalisation), Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Skin exfoliation (n/a - Unknown - Caused/Prolonged Hospitalisation), Xeroderma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7384 | click or scan EU-EC-10010682038 | | 2021-11-18 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Organising pneumonia (24d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | ARAVA [LEFLUNOMIDE] (S - Psoriatic arthropathy - n/a - [n/a - n/a - Oral]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), MULTAQ [DRONEDARONE] (S - Atrial fibrillation - n/a - [n/a - n/a - Oral]), [METHYLPREDNISOLONE] (S - Hyperthyroidism - n/a - [n/a - 8mg - Oral]) |
| 7385 | click or scan EU-EC-10010681890 | | 2021-11-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Intracranial aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7386 | click or scan EU-EC-10010681844 | | 2021-11-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7387 | click or scan EU-EC-10010681506 |  | 2021-11-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Body temperature normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile convulsion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7388 | click or scan EU-EC-10010681431 |  | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7389 | click or scan EU-EC-10010681397 |  | 2021-11-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7390 | click or scan EU-EC-10010681295 |  | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7391 | click or scan EU-EC-10010681251 |  | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 7392 | click or scan EU-EC-10010681232 |  | 2021-11-18 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7393 | click or scan EU-EC-10010681231 |  | 2021-11-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Myocardial infarction (55d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7394 | click or scan EU-EC-10010681139 |  | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 7395 | click or scan EU-EC-10010681124 |  | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7396 | click or scan EU-EC-10010681117 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7397 | click or scan EU-EC-10010681116 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7398 | click or scan EU-EC-10010681088 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7399 | click or scan EU-EC-10010681040 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7400 | click or scan EU-EC-10010681024 | | 2021-11-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Bradycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Disorientation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperreflexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypokinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoventilation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Photopsia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Psychomotor hyperactivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupils unequal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Shock haemorrhagic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tenderness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Verbigeration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7401 | click or scan EU-EC-10010680888 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7402 | click or scan EU-EC-10010680830 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7403 | click or scan EU-EC-10010680581 | | 2021-11-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7404 | click or scan EU-EC-10010680537 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 7405 | click or scan EU-EC-10010680509 | | 2021-11-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7406 | click or scan EU-EC-10010680325 | | 2021-11-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Imaging procedure abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7407 | click or scan EU-EC-10010679675 | | 2021-11-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7408 | click or scan EU-EC-10010679492 | | 2021-11-18 | Healthcare Professional | EEA | 65-85 Years | Female | Acute pulmonary oedema (1d - Fatal - **Results in Death**), Cardiac failure (1d - Fatal - **Results in Death**), Cardiomyopathy (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7409 | click or scan EU-EC-10010678073 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Culture positive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea paroxysmal nocturnal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Orthopnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory viral panel (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventilation/perfusion scan normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Wheezing (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7410 | click or scan EU-EC-10010677061 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Unknown - ), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatitis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pulmonary fibrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 7411 | click or scan EU-EC-10010676514 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7412 | click or scan EU-EC-10010676284 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (1d - Fatal - **Results in Death**), Chills (1d - Fatal - **Results in Death**), Extra dose administered (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7413 | click or scan EU-EC-10010676019 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Male | Gastric haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 7414 | click or scan EU-EC-10010675935 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7415 | click or scan EU-EC-10010675899 | | 2021-11-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7416 | click or scan EU-EC-10010675812 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7417 | click or scan EU-EC-10010675349 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7418 | click or scan EU-EC-10010675104 | | 2021-11-17 | Non Healthcare Professional | EEA | Not Specified | Male | Foetal malformation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7419 | click or scan EU-EC-10010675015 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [132d - 2 {DF} - Intramuscular]) |
| 7420 | click or scan EU-EC-10010674452 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Road traffic accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 7421 | click or scan EU-EC-10010674197 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7422 | click or scan EU-EC-10010673960 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7423 | click or scan EU-EC-10010673888 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cognitive disorder (n/a - Fatal - **Results in Death**), Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 7424 | click or scan EU-EC-10010673839 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7425 | click or scan EU-EC-10010673350 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7426** | click or scan EU-EC-10010673041 | | 2021-11-17 | Healthcare Professional | EEA | More than 85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7427** | click or scan EU-EC-10010673029 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7428** | click or scan EU-EC-10010672969 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7429** | click or scan EU-EC-10010672944 | | 2021-11-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7430** | click or scan EU-EC-10010672770 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiovascular disorder (14d - Fatal - **Results in Death**), Death (14d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7431** | click or scan EU-EC-10010672691 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Ileus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7432** | click or scan EU-EC-10010672650 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7433** | click or scan EU-EC-10010672612 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **7434** | click or scan EU-EC-10010672607 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Marasmus (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7435** | click or scan EU-EC-10010672590 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7436 | click or scan EU-EC-10010672588 |  | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7437 | click or scan EU-EC-10010672587 |  | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7438 | click or scan EU-EC-10010672562 |  | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Hypopnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7439 | click or scan EU-EC-10010672546 |  | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7440 | click or scan EU-EC-10010672538 |  | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7441 | click or scan EU-EC-10010672182 |  | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray abnormal (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mouth haemorrhage (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tracheal haemorrhage (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7442 | click or scan EU-EC-10010672145 |  | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7443 | click or scan EU-EC-10010672111 |  | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Facial asymmetry (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7444 | click or scan EU-EC-10010672110 |  | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), [TOZINAMERAN] (S - n/a - Unknown - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7445 | click or scan EU-EC-10010672110 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), [TOZINAMERAN] (S - n/a - Unknown - [1d - n/a - n/a]) |
| 7446 | click or scan EU-EC-10010672028 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 7447 | click or scan EU-EC-10010671896 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Amnesia (85d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (85d - Fatal - **Results in Death**), Feeling abnormal (85d - Fatal - **Results in Death**), Haemorrhage (85d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (85d - Fatal - **Results in Death**), Loss of consciousness (85d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (85d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (85d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 7448 | click or scan EU-EC-10010671883 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7449 | click or scan EU-EC- | | 2021-11-17 | Non Healthcare | EEA | 18-64 Years | Male | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Influenza (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), [B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), |

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| # | EU Local Number | | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT (Duration - Outcome - Seriousness Criteria) | Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken? - Duration - Dose - Route) |
|---|---|---|---|---|---|---|---|---|---|
| | 10010671259 | | | Professional | | | | | B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) |
| | | | | | | | | | (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), A/CALIFORNIA/7/2009 (H1N1)PDM09 - DERIVED STRAIN USED NYMC X-179A, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **7450** | click or scan EU-EC-10010671141 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **7451** | click or scan EU-EC-10010671005 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7452** | click or scan EU-EC-10010670802 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7453** | click or scan EU-EC-10010670656 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7454** | click or scan EU-EC-10010670474 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bundle branch block right (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung infiltration (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung opacity (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pleural effusion (18d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7455 | click or scan EU-EC-10010670422 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 7456 | click or scan EU-EC-10010670394 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Adenocarcinoma gastric (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic left ventricular failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7457 | click or scan EU-EC-10010670297 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7458 | click or scan EU-EC-10010670179 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**), Cough (17d - Fatal - **Results in Death**), Pneumonia (17d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7459 | click or scan EU-EC-10010670178 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7460 | click or scan EU-EC-10010670157 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anal incontinence (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram normal (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hallucination (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyporesponsive to stimuli (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laboratory test (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental disorder (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 7461 | click or scan EU-EC-10010670079 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7462 | click or scan EU-EC-10010670021 | | 2021-11-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Unknown - Other Medically Important Condition), Body temperature increased (n/a - Unknown - ), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - ), Myalgia (1d - Fatal - **Results in Death**), Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7463 | click or scan EU-EC-10010670006 | | 2021-11-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7464 | click or scan EU-EC-10010669974 | | 2021-11-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7465 | click or scan EU-EC-10010669805 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Head injury (n/a - Unknown - ), Injection site ulcer (n/a - Unknown - ), Malaise (n/a - Unknown - ), Neck pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7466 | click or scan EU-EC-10010669788 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7467 | click or scan EU-EC-10010669099 | | 2021-11-17 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 7468 | click or scan EU-EC-10010668748 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7469 | click or scan EU-EC-10010668696 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anti-neutrophil cytoplasmic antibody positive vasculitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pulmonary alveolar haemorrhage (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Slow speech (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7470 | click or scan EU-EC-10010668693 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7471 | click or scan EU-EC-10010668690 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7472 | click or scan EU-EC-10010668673 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Basilar artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain stem infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neck pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neuropathy peripheral (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7473 | click or scan EU-EC-10010668660 | | 2021-11-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7474 | click or scan EU-EC-10010668659 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Unknown - ), Severe invasive streptococcal infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7475 | click or scan EU-EC-10010668649 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Enterocolitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal perforation (n/a - Fatal - **Results in Death**), Peritonitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7476 | click or scan EU-EC-10010668645 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Breast cancer stage IV (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7477 | click or scan EU-EC-10010668632 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7478 | click or scan EU-EC-10010668624 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7479 | click or scan EU-EC-10010668617 | | 2021-11-17 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Blood pressure systolic decreased (n/a - Recovering/Resolving - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - ), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7480 | click or scan EU-EC-10010668609 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7481 | click or scan EU-EC-10010668386 | | 2021-11-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7482 | click or scan EU-EC-10010666570 | | 2021-11-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Coma (51d - Fatal - **Results in Death**), Death (51d - Fatal - **Results in Death**), Headache (51d - Fatal - **Results in Death**), Hypoaesthesia (51d - Fatal - **Results in Death**), Peripheral swelling (51d - Fatal - **Results in Death**), Thrombosis (51d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 7483 | click or scan EU-EC-10010666452 | | 2021-11-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (2d - Fatal - **Results in Death**), Respiratory failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7484 | click or scan EU-EC-10010665205 | | 2021-11-16 | Healthcare Professional | Non EEA | Not Specified | Male | Acute pulmonary oedema (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung cancer metastatic (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7485 | click or scan EU-EC-10010664526 | | 2021-11-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Type 1 diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7486 | click or scan EU-EC-10010664515 | | 2021-11-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7487 | click or scan EU-EC-10010664176 | | 2021-11-16 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular]) |
| 7488 | click or scan EU-EC-10010662625 | | 2021-11-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) |
| 7489 | click or scan EU-EC-10010662593 | | 2021-11-16 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| 7490 | click or scan EU-EC-10010661987 | | 2021-11-16 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 7491 | click or scan EU-EC-10010661985 | | 2021-11-16 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Parenteral]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Myocardial ischaemia - Drug withdrawn - [n/a - 1{DF} - Oral]) |
| 7492 | click or scan EU-EC-10010661972 | | 2021-11-16 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7493 | click or scan EU-EC-10010661885 | | 2021-11-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7494 | click or scan EU-EC-10010661617 | | 2021-11-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central nervous system infection (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eyelid ptosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical condition abnormal (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypersomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Memory impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Retroperitoneal haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tenderness (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 7495 | click or scan EU-EC-10010661451 | | 2021-11-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac tamponade (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7496 | click or scan EU-EC-10010660160 | | 2021-11-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7497 | click or scan EU-EC-10010660159 | | 2021-11-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Cerebral infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7498 | click or scan EU-EC-10010660144 | | 2021-11-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7499 | click or scan EU-EC-10010659567 | | 2021-11-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Discomfort (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hypersomnia (n/a - Unknown - ), Illness (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7500 | click or scan EU-EC-10010658415 | | 2021-11-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7501 | click or scan EU-EC-10010656729 | | 2021-11-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Femoral neck fracture (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7502 | click or scan EU-EC-10010656587 | | 2021-11-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dizziness (138d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalitis autoimmune (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Memory impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7503 | click or scan EU-EC-10010656465 | | 2021-11-16 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Malaise (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 7504 | click or scan EU-EC-10010656374 | | 2021-11-16 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Anomalous pulmonary venous connection (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Atrial septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Congenital great vessel anomaly (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Death neonatal (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Recovered/Resolved - Congenital Anomaly, Other Medically Important Condition), Heterotaxia (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Multiple congenital abnormalities (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Ventricular hypoplasia (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition) | [SERTRALINE, SERTRALINE HYDROCHLORIDE] (S - Anxiety - Dose not changed - [n/a - 50mg - Transplacental]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (S - n/a - Not applicable - [n/a - 50mg - Oral]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 7505 | click or scan EU-EC-10010655849 | | 2021-11-16 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 7506 | click or scan EU-EC-10010654988 | | 2021-11-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| | | | | | | | | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [DIPHTHERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, DIPHTHERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, |

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|---|---|---|---|---|---|---|---|---|---|
| 7507 | click or scan<br>EU-EC-10010654973 | | 2021-11-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Product use issue (n/a - Fatal - **Results in Death**) | POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), DIPHTHERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHTHERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), ALUMINIUM HYDROXIDE, FILAMENTOUS HAEMAGGLUTININ, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM HYDROXIDE, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, PERTUSSIS TOXOID ADSORBED ON |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT (Duration - Outcome - Seriousness Criteria) | Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | ALUMINIUM HYDROXIDE, HYDRATED, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, ALGELDRATE] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7508** | click or scan EU-EC-10010654902 | | 2021-11-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - .3 mL - Intramuscular]) |
| **7509** | click or scan EU-EC-10010653687 | | 2021-11-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **7510** | click or scan EU-EC-10010653154 | | 2021-11-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Tinnitus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **7511** | click or scan EU-EC-10010653122 | | 2021-11-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pneumonitis (3 d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3 mL - Intramuscular]) |
| **7512** | click or scan EU-EC-10010652792 | | 2021-11-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Status epilepticus (12 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **7513** | click or scan EU-EC-10010652772 | | 2021-11-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7514 | click or scan EU-EC-10010652320 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiopathy (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7515 | click or scan EU-EC-10010651963 | | 2021-11-15 | Healthcare Professional | Non EEA | Not Specified | Male | Adverse drug reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7516 | click or scan EU-EC-10010651961 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood potassium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cavernous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7517 | click or scan EU-EC-10010651958 | | 2021-11-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Cough (n/a - Recovered/Resolved - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7518 | click or scan EU-EC-10010651926 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7519 | click or scan EU-EC-10010651867 | | 2021-11-15 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 7520 | click or scan EU-EC-10010651241 | | 2021-11-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspepsia (n/a - Unknown - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - **Results in Death**), Off label use (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [COVID-19 VACCINE] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| 7521 | click or scan EU-EC-10010650988 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7522 | click or scan EU-EC-10010650985 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7523 | click or scan EU-EC-10010650974 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7524 | click or scan EU-EC-10010650830 | | 2021-11-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - ), Abdominal pain upper (n/a - Unknown - ), Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pallor (n/a - Unknown - ), Purpura (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Thirst (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7525 | click or scan EU-EC-10010650602 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hot flush (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7526 | click or scan EU-EC-10010650599 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7527 | click or scan EU-EC-10010650497 | | 2021-11-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hallucination (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7528 | click or scan EU-EC-10010650351 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7529 | click or scan EU-EC-10010650245 | | 2021-11-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7530 | click or scan EU-EC-10010649885 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7531 | click or scan EU-EC-10010649688 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Impaired healing (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7532 | click or scan EU-EC-10010649576 | | 2021-11-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7533 | click or scan EU-EC-10010649223 | | 2021-11-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cachexia (n/a - Fatal - **Results in Death**), Nausea (45d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7534 | click or scan EU-EC-10010649068 | | 2021-11-15 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Brain oedema (n/a - Fatal - **Results in Death**), Confusional state (n/a - Unknown - ), Dysarthria (n/a - Unknown - ), Headache (n/a - Unknown - ), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Speech disorder (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7535 | click or scan EU-EC-10010648902 | | 2021-11-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pain in extremity (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 7536 | click or scan EU-EC-10010648757 | | 2021-11-15 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7537 | click or scan EU-EC-10010648715 | | 2021-11-15 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 7538 | click or scan EU-EC-10010648576 | | 2021-11-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (6d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [21d - .3mL - Intramuscular]) |
| 7539 | click or scan EU-EC-10010648428 | | 2021-11-15 | Healthcare Professional | EEA | More than 85 Years | Male | Haemorrhagic stroke (1d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [AMOXICILLIN, AMOXICILLIN SODIUM, AMOXICILLIN TRIHYDRATE] (S - Bronchitis - Drug withdrawn - [7d - 1g - Oral]) |
| 7540 | click or scan EU-EC-10010648381 | | 2021-11-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7541 | click or scan EU-EC-10010648318 | | 2021-11-15 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7542 | click or scan EU-EC-10010647939 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7543 | click or scan EU-EC-10010647935 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Hypokalaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7544** | click or scan EU-EC-10010647809 | | 2021-11-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Craniocerebral injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7545** | click or scan EU-EC-10010647792 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **7546** | click or scan EU-EC-10010647785 | | 2021-11-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7547** | click or scan EU-EC-10010647153 | | 2021-11-15 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **7548** | click or scan EU-EC-10010645941 | | 2021-11-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7549** | click or scan EU-EC-10010645857 | | 2021-11-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple sclerosis relapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subileus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7550** | click or scan EU-EC-10010645849 | | 2021-11-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7551** | click or scan EU-EC-10010645844 | | 2021-11-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7552** | click or scan EU-EC-10010645843 | | 2021-11-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **7553** | click or scan EU-EC-10010645839 | | 2021-11-15 | Non Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7554 | click or scan EU-EC-10010645694 | | 2021-11-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7555 | click or scan EU-EC-10010645576 | | 2021-11-15 | Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Plasma cell leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7556 | click or scan EU-EC-10010645523 | | 2021-11-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7557 | click or scan EU-EC-10010644690 | | 2021-11-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7558 | click or scan EU-EC-10010644202 | | 2021-11-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac valve disease (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cardiac valve vegetation (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7559 | click or scan EU-EC-10010643282 | | 2021-11-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7560 | click or scan EU-EC-10010642459 | | 2021-11-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Injection site reaction (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7561 | click or scan EU-EC-10010641267 | | 2021-11-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7562 | click or scan EU-EC-10010637417 | | 2021-11-12 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 7563 | click or scan EU-EC-10010637325 | | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7564 | click or scan EU-EC-10010637234 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Agonal respiration (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Amnesia (n/a - Not Recovered/Not Resolved - ), Apallic syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyskinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Head injury (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Somnolence (n/a - Unknown - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site erythema (n/a - Not Recovered/Not Resolved - ), Vaccination site rash (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7565 | click or scan EU-EC-10010637173 | | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Female | Portosplenomesenteric venous thrombosis (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 7566 | click or scan EU-EC-10010637051 | | 2021-11-12 | Non Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Unknown - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Myocarditis (n/a - Unknown - **Results in Death**), Palpitations (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**), Tachycardia (n/a - Unknown - **Results in Death**) | [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 7567 | click or scan EU-EC-10010636789 | | 2021-11-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7568 | click or scan EU-EC-10010636785 | | 2021-11-12 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Cerebral haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperpyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Superior sagittal sinus thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7569 | click or scan EU-EC-10010636715 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7570 | click or scan EU-EC-10010636548 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Hepatic function abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7571 | click or scan EU-EC-10010636058 |  | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - Other Medically Important Condition), Blood fibrinogen increased (n/a - Unknown - Other Medically Important Condition), Cerebellar infarction (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Endocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Splenomegaly (n/a - Unknown - Other Medically Important Condition), Staphylococcal sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7572 | click or scan EU-EC-10010636047 |  | 2021-11-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7573 | click or scan EU-EC-10010635889 |  | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mydriasis (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7574 | click or scan EU-EC-10010635676 |  | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7575 | click or scan EU-EC-10010635287 |  | 2021-11-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7576 | click or scan EU-EC-10010635279 |  | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7577 | click or scan EU-EC-10010635141 |  | 2021-11-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Full blood count abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7578 | click or scan EU-EC-10010635099 |  | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7579 | click or scan EU-EC-10010634403 |  | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7580 | click or scan EU-EC-10010633697 | | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3{DF} - Intramuscular]) |
| 7581 | click or scan EU-EC-10010633678 | | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 7582 | click or scan EU-EC-10010633577 | | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (20d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a]) |
| 7583 | click or scan EU-EC-10010633501 | | 2021-11-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7584 | click or scan EU-EC-10010633388 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7585 | click or scan EU-EC-10010633105 | | 2021-11-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 7586 | click or scan EU-EC-10010632999 | | 2021-11-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7587 | click or scan EU-EC-10010632994 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Respiratory disorder (n/a - Unknown - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7588 | click or scan EU-EC-10010632970 | | 2021-11-12 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7589 | click or scan EU-EC-10010632874 | | 2021-11-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Epistaxis (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7590 | click or scan EU-EC-10010632869 | | 2021-11-12 | Healthcare Professional | Non EEA | Not Specified | Female | Abortion spontaneous (n/a - Unknown - Congenital Anomaly), Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly), Stillbirth (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [0mo - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7591 | click or scan EU-EC-10010632529 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7592 | click or scan EU-EC-10010632376 | | 2021-11-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7593 | click or scan EU-EC-10010632370 | | 2021-11-12 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral ischaemia (26d - Fatal - **Results in Death**), Hemiparesis (26d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7594 | click or scan EU-EC-10010632287 | | 2021-11-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Language disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7595 | click or scan EU-EC-10010631973 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Rales (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7596 | click or scan EU-EC-10010631965 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - ), Blood lactic acid increased (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Haematoma (n/a - Unknown - ), Hypoxia (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Liver contusion (n/a - Unknown - Other Medically Important Condition), Liver injury (n/a - Unknown - Other Medically Important Condition), Metabolic acidosis (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory acidosis (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vascular pseudoaneurysm (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7597 | click or scan EU-EC-10010631948 | | 2021-11-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neck pain (n/a - Unknown - Other Medically Important Condition), Oesophageal pain (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7598 | click or scan EU-EC-10010631794 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7599 | click or scan EU-EC-10010631619 | | 2021-11-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Not Recovered/Not Resolved - Life Threatening), Discomfort (n/a - Fatal - **Results in Death**, Life Threatening), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening), Fall (n/a - Not Recovered/Not Resolved - Life Threatening), Head injury (n/a - Not Recovered/Not Resolved - Life Threatening), Headache (n/a - Not Recovered/Not Resolved - Life Threatening), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Syncope (n/a - Fatal - **Results in Death**), Taste disorder (n/a - Not Recovered/Not Resolved - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7600** | click or scan EU-EC-10010631608 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7601** | click or scan EU-EC-10010631565 | | 2021-11-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7602** | click or scan EU-EC-10010631496 | | 2021-11-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebellar tumour (n/a - Fatal - **Results in Death**), Fatigue (193d - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Injection site inflammation (n/a - Recovered/Resolved - ), Injection site pain (n/a - Recovered/Resolved - ), Injection site swelling (n/a - Recovered/Resolved - ), Rash macular (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **7603** | click or scan EU-EC-10010631117 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Encephalitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7604** | click or scan EU-EC-10010630946 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7605** | click or scan EU-EC-10010630917 | | 2021-11-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **7606** | click or scan EU-EC-10010630256 | | 2021-11-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **7607** | click or scan EU-EC-10010629648 | | 2021-11-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7608 | click or scan EU-EC-10010629316 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haematemesis (3599min - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (64h - Fatal - **Results in Death**), Rash (388h - Fatal - **Results in Death**), Vaccination site pain (388h - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 7609 | click or scan EU-EC-10010629100 | | 2021-11-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7610 | click or scan EU-EC-10010629028 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7611 | click or scan EU-EC-10010628865 | | 2021-11-12 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7612 | click or scan EU-EC-10010628842 | | 2021-11-12 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7613 | click or scan EU-EC-10010628755 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 7614 | click or scan EU-EC-10010628638 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Azotaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hydrocephalus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7615 | click or scan EU-EC-10010628481 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Carotid artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7616 | click or scan EU-EC-10010628450 | | 2021-11-12 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Abnormal behaviour (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Lack of spontaneous speech (n/a - Fatal - **Results in Death**), Slow speech (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7617 | click or scan EU-EC-10010628440 | | 2021-11-12 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Confusional state (6h - Recovered/Resolved - ), Diplopia (0d - Recovered/Resolved - ), Dizziness (n/a - Unknown - ), Dysarthria (0d - Recovered/Resolved - ), Fall (n/a - Unknown - ), Lower respiratory tract congestion (0d - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (0d - Recovered/Resolved - ), Psychomotor skills impaired (0d - Recovered/Resolved - ), Pyrexia (0d - Recovered/Resolved - ), Sedation (6h - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7618 | click or scan EU-EC-10010628061 | | 2021-11-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7619 | click or scan EU-EC-10010627191 | | 2021-11-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 7620 | click or scan EU-EC-10010626936 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7621 | click or scan EU-EC-10010626935 | | 2021-11-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7622 | click or scan EU-EC-10010626855 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (7 d - Fatal - **Results in Death**), Neonatal dyspnoea (7 d - Fatal - **Results in Death**), Palpitations (7 d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7623 | click or scan EU-EC-10010626678 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7624 | click or scan EU-EC-10010626677 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Red blood cell count decreased (n/a - Fatal - **Results in Death**), SARS-CoV-2 antibody test positive (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7625 | click or scan EU-EC-10010626490 | | 2021-11-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ), Dehydration (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7626 | click or scan EU-EC-10010626464 | | 2021-11-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute lymphocytic leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7627 | click or scan EU-EC-10010626085 | | 2021-11-12 | Healthcare Professional | EEA | Not Specified | Male | Thrombocytopenia (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7628 | click or scan EU-EC-10010625760 | | 2021-11-12 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (17d - Fatal - **Results in Death**), Cough (17d - Fatal - **Results in Death**), Disseminated intravascular coagulation (17d - Fatal - **Results in Death**), Hepatitis acute (17d - Fatal - **Results in Death**), Pyrexia (17d - Fatal - **Results in Death**), Systemic inflammatory response syndrome (17d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 7629 | click or scan EU-EC-10010625694 | | 2021-11-12 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 7630 | click or scan EU-EC-10010624484 | | 2021-11-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7631 | click or scan EU-EC-10010624373 | | 2021-11-11 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 7632 | click or scan EU-EC-10010624262 | | 2021-11-11 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Ataxia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, IVR-208), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE)] (S - Influenza immunisation - Not applicable - [n/a - .7mL - Intramuscular]) |
| 7633 | click or scan EU-EC-10010624058 | | 2021-11-11 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (3d - Fatal - **Results in Death**), Escherichia sepsis (3d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (3d - Fatal - **Results in Death**), Pyrexia (6d - Fatal - **Results in Death**), Thrombocytopenia (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, NIB-104), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A)] (S - Prophylaxis - Not applicable - [1d - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7634 | click or scan EU-EC-10010623010 | | 2021-11-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunology test (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7635 | click or scan EU-EC-10010622923 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7636 | click or scan EU-EC-10010622891 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bradycardia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7637 | click or scan EU-EC-10010622885 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic arteriosclerosis (3d - Fatal - **Results in Death**, Other Medically Important Condition), Bronchogenic cyst (3d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (3d - Fatal - **Results in Death**), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Other Medically Important Condition), Colitis (3d - Fatal - **Results in Death**), Diverticulum intestinal (3d - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (3d - Fatal - **Results in Death**), Gastrointestinal wall thickening (3d - Fatal - **Results in Death**), Hepatic lesion (3d - Fatal - **Results in Death**), Hiatus hernia (3d - Fatal - **Results in Death**), Lymphadenopathy (3d - Fatal - **Results in Death**), Metastases to liver (3d - Fatal - **Results in Death**, Other Medically Important Condition), Metastases to lung (3d - Fatal - **Results in Death**, Other Medically Important Condition), Metastases to spleen (3d - Fatal - **Results in Death**, Other Medically Important Condition), Necrotic lymphadenopathy (3d - Fatal - **Results in Death**, Other Medically Important Condition), Oesophageal oedema (3d - Fatal - **Results in Death**), Osteoarthritis (3d - Fatal - **Results in Death**), Osteopenia (3d - Fatal - **Results in Death**), Pneumonia (3d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary mass (3d - Fatal - **Results in Death**), Pulmonary valve thickening (3d - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7638 | click or scan EU-EC-10010622762 | | 2021-11-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7639 | click or scan EU-EC-10010622529 | | 2021-11-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7640 | click or scan EU-EC-10010622376 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7641 | click or scan EU-EC-10010622310 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Glioblastoma (187d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7642 | click or scan EU-EC-10010622228 | | 2021-11-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7643 | click or scan EU-EC-10010622209 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7644 | click or scan EU-EC-10010622207 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7645 | click or scan EU-EC-10010622103 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dilatation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral small vessel ischaemic disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lacunar infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung infiltration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mental status changes (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial strain imaging (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 antibody test positive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7646 | click or scan EU-EC-10010622080 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Antifungal treatment (n/a - Fatal - **Results in Death**, Life Threatening), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Central venous catheterisation (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening), Fungaemia (n/a - Fatal - **Results in Death**, Life Threatening), Haemofiltration (n/a - Fatal - **Results in Death**, Life Threatening), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening), Renal replacement therapy (n/a - Fatal - **Results in Death**, Life Threatening), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening), Vascular catheterisation (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7647 | click or scan EU-EC-10010622077 | | 2021-11-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic reaction (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7648 | click or scan EU-EC-10010622052 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Atelectasis (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Back pain (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), COVID-19 (27d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Chest pain (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Condition aggravated (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cyanosis (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Disseminated intravascular coagulation (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dysstasia (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Enterococcal bacteraemia (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fluid intake reduced (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hepatic failure (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hyperventilation (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Illness (31d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Impaired self-care (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Influenza (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Oropharyngeal pain (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Painful respiration (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pneumonia (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pseudomonal bacteraemia (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Renal failure (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory arrest (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory tract congestion (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombotic thrombocytopenic purpura (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vaccination complication (32d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7649 | click or scan EU-EC-10010621979 | | 2021-11-11 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Sleep disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7650 | click or scan EU-EC-10010621707 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Feeding disorder (n/a - Fatal - **Results in Death**, Life Threatening), Lethargy (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7651 | click or scan EU-EC-10010621241 | | 2021-11-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7652 | click or scan EU-EC-10010621205 | | 2021-11-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7653 | click or scan EU-EC-10010620642 | | 2021-11-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7654 | click or scan EU-EC-10010620546 | | 2021-11-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7655 | click or scan EU-EC-10010620337 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7656 | click or scan EU-EC-10010620314 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7657 | click or scan EU-EC-10010620097 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dermatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Septic rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Swelling (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7658 | click or scan EU-EC-10010620026 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cellulitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Marasmus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7659 | click or scan EU-EC-10010619825 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7660 | click or scan EU-EC-10010619822 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Autoimmune hepatitis (n/a - Unknown - Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myositis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7661 | click or scan EU-EC-10010619083 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7662 | click or scan EU-EC-10010618811 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abnormal weight gain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ascites (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrolyte imbalance (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric artery thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sarcopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Varices oesophageal (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [0mo - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7663** | click or scan EU-EC-10010618722 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Obstruction gastric (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Obstructive airways disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA VACCINE] (S - Influenza immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **7664** | click or scan EU-EC-10010617653 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7665** | click or scan EU-EC-10010616861 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile infection (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumocystis jirovecii pneumonia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subcutaneous emphysema (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superinfection (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Traumatic lung injury (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7666** | click or scan EU-EC-10010616828 | | 2021-11-11 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Abortion (n/a - Fatal - **Results in Death**), Hypoplastic left heart syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7667** | click or scan EU-EC-10010616819 | | 2021-11-11 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not Resolved - ), Weight decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7668** | click or scan EU-EC-10010616815 | | 2021-11-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7669** | click or scan EU-EC-10010616739 | | 2021-11-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Not Recovered/Not Resolved - ), Non-Hodgkin's lymphoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7670** | click or scan EU-EC-10010616730 | | 2021-11-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7671** | click or scan EU-EC-10010616682 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory distress syndrome (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gout (n/a - Unknown - Caused/Prolonged Hospitalisation), Joint destruction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin ulcer (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7672 | click or scan EU-EC-10010616404 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Exophthalmos (34d - Fatal - **Results in Death**, Other Medically Important Condition), Swelling face (34d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7673 | click or scan EU-EC-10010616236 | | 2021-11-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7674 | click or scan EU-EC-10010616139 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Feeding disorder (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyporesponsive to stimuli (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7675 | click or scan EU-EC-10010616018 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ascites (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacteraemia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), End stage renal disease (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Small intestinal obstruction (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Spontaneous bacterial peritonitis (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7676 | click or scan EU-EC-10010615946 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness postural (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presyncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary mass (n/a - Unknown - Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7677 | click or scan EU-EC-10010615790 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumothorax (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7678 | click or scan EU-EC-10010615736 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7679 | click or scan EU-EC-10010615659 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Vaccine breakthrough infection (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7680 | click or scan EU-EC-10010615634 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7681 | click or scan EU-EC-10010615444 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (219d - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Laryngitis (1d - Fatal - **Results in Death**), Lung infiltration (1d - Fatal - **Results in Death**), Malaise (9d - Fatal - **Results in Death**), Throat tightness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7682 | click or scan EU-EC-10010615409 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain upper (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7683 | click or scan EU-EC-10010615397 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pupil fixed (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7684 | click or scan EU-EC-10010615277 | | 2021-11-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7685 | click or scan EU-EC-10010615250 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | General physical health deterioration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7686 | click or scan EU-EC-10010615047 | | 2021-11-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung consolidation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7687 | click or scan EU-EC-10010615006 | | 2021-11-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Lung opacity (29d - Fatal - **Results in Death**), Metastasis (29d - Fatal - **Results in Death**, Other Medically Important Condition), Musculoskeletal chest pain (29d - Fatal - **Results in Death**), Oedema peripheral (29d - Fatal - **Results in Death**), Pulmonary mass (29d - Fatal - **Results in Death**), Sepsis (29d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7688 | click or scan EU-EC-10010614464 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7689 | click or scan EU-EC-10010614442 | | 2021-11-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7690 | click or scan EU-EC-10010614378 | | 2021-11-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7691 | click or scan EU-EC-10010613621 | | 2021-11-11 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (3d - Fatal - **Results in Death**), Coagulopathy (3d - Fatal - **Results in Death**), Rectal haemorrhage (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7692 | click or scan EU-EC-10010613180 | | 2021-11-10 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7693 | click or scan EU-EC-10010613092 | | 2021-11-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7694 | click or scan EU-EC-10010613049 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - Unknown]) |
| 7695 | click or scan EU-EC-10010613006 | | 2021-11-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Feeling hot (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7696 | click or scan EU-EC-10010612788 | | 2021-11-10 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 7697 | click or scan EU-EC-10010612726 | | 2021-11-10 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laryngeal oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 7698 | click or scan EU-EC-10010612700 | | 2021-11-10 | Non Healthcare Professional | EEA | Not Specified | Female | Chest pain (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Palpitations (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Purpura (n/a - Not Recovered/Not Resolved - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**), Tachycardia (n/a - Unknown - **Results in Death**) | [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7699** | click or scan EU-EC-10010612434 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial flutter (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - Unknown]) |
| **7700** | click or scan EU-EC-10010612336 | | 2021-11-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (3d - Fatal - **Results in Death**), Chest pain (3d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Hypertension (1d - Fatal - **Results in Death**), Paralysis (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Tachycardia (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **7701** | click or scan EU-EC-10010612294 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7702** | click or scan EU-EC-10010612262 | | 2021-11-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myelodysplastic syndrome (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7703** | click or scan EU-EC-10010612248 | | 2021-11-10 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7704** | click or scan EU-EC-10010612182 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Supraventricular tachycardia (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7705** | click or scan EU-EC-10010612089 | | 2021-11-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7706** | click or scan EU-EC-10010611698 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7707** | click or scan EU-EC-10010611628 | | 2021-11-10 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal heart rate abnormal (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal heart rate decreased (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **7708** | click or scan EU-EC-10010611308 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - ), Malaise (1d - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7709 | click or scan EU-EC-10010611299 | | 2021-11-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dependence on respirator (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7710 | click or scan EU-EC-10010611235 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Extubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 7711 | click or scan EU-EC-10010611211 | | 2021-11-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7712 | click or scan EU-EC-10010611180 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7713 | click or scan EU-EC-10010611178 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7714 | click or scan EU-EC-10010611114 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Communication disorder (146d - Fatal - **Results in Death**), Confusional state (146d - Fatal - **Results in Death**), Mental impairment (146d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7715 | click or scan EU-EC-10010611100 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (10d - Fatal - **Results in Death**), Drug ineffective (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7716 | click or scan EU-EC-10010610164 | | 2021-11-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Coma (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7717 | click or scan EU-EC-10010610102 | | 2021-11-10 | Non Healthcare Professional | EEA | Not Specified | Male | Exposure during pregnancy (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7718 | click or scan EU-EC-10010610077 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 7719 | click or scan EU-EC-10010609865 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7720 | click or scan EU-EC-10010608764 | | 2021-11-10 | Healthcare Professional | EEA | 65-85 Years | Female | Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7721 | click or scan EU-EC-10010608070 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - ), Eating disorder (n/a - Fatal - **Results in Death**, Life Threatening), Heart rate increased (n/a - Unknown - ), Hepatic function abnormal (n/a - Fatal - **Results in Death**), Oedema (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7722 | click or scan EU-EC-10010608039 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Disease progression (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7723 | click or scan EU-EC-10010608005 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Complication associated with device (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Contrast media reaction (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding disorder (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid intake reduced (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in jaw (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal disorder (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Systemic infection (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7724 | click or scan EU-EC-10010607838 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**), Body temperature increased (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7725 | click or scan EU-EC-10010607798 | | 2021-11-10 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7726 | click or scan EU-EC-10010607772 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Emphysema (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Pneumothorax (n/a - Fatal - **Results in Death**), Traumatic haemothorax (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ), Vaccination site pruritus (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7727 | click or scan EU-EC-10010607686 | | 2021-11-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7728 | click or scan EU-EC-10010607635 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7729 | click or scan EU-EC-10010607630 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7730 | click or scan EU-EC-10010607629 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Chronic kidney disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7731 | click or scan EU-EC-10010607583 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7732 | click or scan EU-EC-10010607576 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7733 | click or scan EU-EC-10010607358 | | 2021-11-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (0d - Fatal - **Results in Death**), Cerebral haemorrhage (0d - Fatal - **Results in Death**), Fall (0d - Fatal - **Results in Death**), Skull fracture (0d - Fatal - **Results in Death**), Subdural haematoma (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7734 | click or scan EU-EC-10010607180 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7735 | click or scan EU-EC-10010606678 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7736 | click or scan EU-EC-10010605829 |  | 2021-11-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - n/a]) |
| 7737 | click or scan EU-EC-10010605567 |  | 2021-11-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aortic dissection rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid artery stenosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular stenosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Drainage (n/a - Unknown - Caused/Prolonged Hospitalisation), Femoral artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Groin pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Intrapericardial thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Orchitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral artery surgery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Precerebral artery occlusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Testicular abscess (n/a - Unknown - Caused/Prolonged Hospitalisation), Testicular operation (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7738 | click or scan EU-EC-10010604875 |  | 2021-11-10 | Healthcare Professional | EEA | 65-85 Years | Male | Metastatic bronchial carcinoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 7739 | click or scan EU-EC-10010604376 |  | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7740 | click or scan EU-EC-10010604350 |  | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7741 | click or scan EU-EC-10010604020 |  | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7742 | click or scan EU-EC-10010603882 |  | 2021-11-10 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (1d - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7743 | click or scan EU-EC-10010603804 |  | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Unknown - ), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Hypophagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleurisy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rales (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7744 | click or scan EU-EC-10010603786 |  | 2021-11-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7745 | click or scan EU-EC-10010603750 | | 2021-11-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7746 | click or scan EU-EC-10010603616 | | 2021-11-10 | Healthcare Professional | EEA | More than 85 Years | Female | Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7747 | click or scan EU-EC-10010603551 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (3d - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7748 | click or scan EU-EC-10010603453 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7749 | click or scan EU-EC-10010603451 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (29d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7750 | click or scan EU-EC-10010603389 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7751 | click or scan EU-EC-10010602878 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7752 | click or scan EU-EC-10010602811 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7753 | click or scan EU-EC-10010602676 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7754 | click or scan EU-EC-10010602669 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7755 | click or scan EU-EC-10010602615 | | 2021-11-10 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7756 | click or scan EU-EC-10010602611 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7757 | click or scan EU-EC-10010602578 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7758 | click or scan EU-EC-10010602472 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7759 | click or scan EU-EC-10010602450 | | 2021-11-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7760 | click or scan EU-EC-10010602441 | | 2021-11-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7761 | click or scan EU-EC-10010602289 | | 2021-11-10 | Healthcare Professional | EEA | More than 85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Haemorrhagic stroke (2d - Fatal - **Results in Death**), Thalamus haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7762 | click or scan EU-EC-10010601647 | | 2021-11-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 7763 | click or scan EU-EC-10010598116 | | 2021-11-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7764 | click or scan EU-EC-10010597979 | | 2021-11-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7765 | click or scan EU-EC-10010597074 | | 2021-11-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Drowning (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7766 | click or scan EU-EC-10010596892 | | 2021-11-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7767 | click or scan EU-EC-10010596701 | | 2021-11-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Depression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7768 | click or scan EU-EC-10010596568 | | 2021-11-09 | Non Healthcare Professional | EEA | Not Specified | Female | Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7769 | click or scan EU-EC-10010596555 | | 2021-11-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dizziness (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7770 | click or scan EU-EC-10010596546 | | 2021-11-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Aortic aneurysm (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Apnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Atrioventricular block first degree (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood gases abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood lactic acid (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood loss anaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood test abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Bundle branch block right (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Central venous catheterisation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram pelvis abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram thorax (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dependence on respirator (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Electrocardiogram normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Electrolyte imbalance (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Explorative laparotomy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Extubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastric ulcer perforation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal fistula (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Infusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Inguinal hernia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7771 | click or scan EU-EC-10010596425 | | 2021-11-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (16d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7772 | click or scan EU-EC-10010596374 | | 2021-11-09 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac valve disease (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cardiac valve vegetation (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7773 | click or scan EU-EC-10010594251 | | 2021-11-09 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7774 | click or scan EU-EC-10010594246 | | 2021-11-09 | Healthcare Professional | EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exercise tolerance decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7775 | click or scan EU-EC-10010594245 | | 2021-11-09 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7776 | click or scan EU-EC-10010594244 | | 2021-11-09 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7777 | click or scan EU-EC-10010594243 | | 2021-11-09 | Healthcare Professional | EEA | More than 85 Years | Female | Left ventricular failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7778 | click or scan EU-EC-10010594110 | | 2021-11-09 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1 d - .3 mL - Intramuscular]) |
| 7779 | click or scan EU-EC-10010594105 | | 2021-11-09 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1 d - .3 mL - Intramuscular]) |
| 7780 | click or scan EU-EC-10010593973 | | 2021-11-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7781 | click or scan EU-EC-10010593971 | | 2021-11-09 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7782 | click or scan EU-EC-10010593953 | | 2021-11-09 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7783 | click or scan EU-EC-10010593952 | | 2021-11-09 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7784 | click or scan EU-EC-10010593951 | | 2021-11-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7785 | click or scan EU-EC-10010593725 | | 2021-11-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**), Vertigo (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7786 | click or scan EU-EC-10010593345 | | 2021-11-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 7787 | click or scan EU-EC-10010592636 | | 2021-11-09 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 7788 | click or scan EU-EC-10010592255 | | 2021-11-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7789 | click or scan EU-EC-10010592176 | | 2021-11-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7790 | click or scan EU-EC-10010592143 | | 2021-11-09 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immunosuppression (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a - More in ICSR]) |
| 7791 | click or scan EU-EC-10010592104 | | 2021-11-09 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal haemorrhage (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), [B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), INFLUENZA A VIRUS, A/CAMBODIA/E0826360/2020 (H3N2) - LIKE STRAIN (A/TASMANIA/503/2020, IVR-221), INACTIVATED] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7792 | click or scan EU-EC-10010592095 | | 2021-11-09 | Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pancreatic carcinoma (6wk - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 7793 | click or scan EU-EC-10010591979 | | 2021-11-09 | Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (47d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (47d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (47d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (47d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (47d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7794 | click or scan EU-EC-10010591365 | | 2021-11-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Product use issue (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7795 | click or scan EU-EC-10010591143 | | 2021-11-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hydrocephalus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7796 | click or scan EU-EC-10010589566 | | 2021-11-09 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7797 | click or scan EU-EC-10010589463 | | 2021-11-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7798 | click or scan EU-EC-10010588261 | | 2021-11-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7799 | click or scan EU-EC-10010588075 | | 2021-11-09 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate abnormal (n/a - Fatal - **Results in Death**), Foetal hypokinesia (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 7800 | click or scan EU-EC-10010587992 | | 2021-11-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), Abdominal distension (n/a - Recovering/Resolving - Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**), Heat illness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7801 | click or scan EU-EC-10010587943 | | 2021-11-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral artery occlusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7802 | click or scan EU-EC-10010586862 | | 2021-11-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7803 | click or scan EU-EC-10010585462 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (8d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Dizziness (6d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Malaise (6d - Fatal - **Results in Death**), Pyrexia (7d - Fatal - **Results in Death**), Throat irritation (8d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7804 | click or scan EU-EC-10010585045 | | 2021-11-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 7805 | click or scan EU-EC-10010584747 | | 2021-11-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7806 | click or scan EU-EC-10010584437 | | 2021-11-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7807 | click or scan EU-EC-10010584395 | | 2021-11-08 | Non Healthcare Professional | EEA | Not Specified | Female | Dizziness (n/a - Unknown - ), Fall (n/a - Unknown - ), Gastrointestinal inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematochezia (n/a - Unknown - ), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7808 | click or scan EU-EC-10010584148 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anxiety (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood gases (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Emphysema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Patient restraint (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Treatment noncompliance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7809 | click or scan EU-EC-10010583661 | | 2021-11-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7810 | click or scan EU-EC-10010583594 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7811 | click or scan EU-EC-10010582866 | | 2021-11-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7812 | click or scan EU-EC-10010582788 | | 2021-11-08 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7813 | click or scan EU-EC-10010582157 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2 {DF} - Intramuscular]) |
| 7814 | click or scan EU-EC-10010581971 | | 2021-11-08 | Healthcare Professional | EEA | More than 85 Years | Female | Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [31d - 1 {DF} - Intramuscular]) |
| 7815 | click or scan EU-EC-10010581969 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [28d - 1 {DF} - Intramuscular]) |
| 7816 | click or scan EU-EC-10010581965 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [28d - 1 {DF} - Intramuscular]) |
| 7817 | click or scan EU-EC-10010581956 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [21d - 1 {DF} - Intramuscular]) |
| 7818 | click or scan EU-EC-10010581923 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mg - Intramuscular]) |
| 7819 | click or scan EU-EC-10010581864 | | 2021-11-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haematoma (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7820 | click or scan EU-EC-10010581857 | | 2021-11-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ruptured cerebral aneurysm (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - .3mL - Intramuscular]) |
| 7821 | click or scan EU-EC-10010581829 | | 2021-11-08 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7822 | click or scan EU-EC-10010581819 | | 2021-11-08 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7823 | click or scan EU-EC-10010581781 | | 2021-11-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Agitation (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Electrocardiogram T wave abnormal (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), QRS axis abnormal (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7824 | click or scan EU-EC-10010581660 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7825 | click or scan EU-EC-10010581658 | | 2021-11-08 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7826 | click or scan EU-EC-10010581068 | | 2021-11-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7827 | click or scan EU-EC-10010580917 | | 2021-11-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (3020min - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7828 | click or scan EU-EC-10010580667 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Immunisation (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7829 | click or scan EU-EC-10010580610 | | 2021-11-08 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia viral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7830 | click or scan EU-EC-10010580576 | | 2021-11-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7831 | click or scan EU-EC-10010580459 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7832 | click or scan EU-EC-10010580430 | | 2021-11-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 7833 | click or scan EU-EC-10010580030 | | 2021-11-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspepsia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7834 | click or scan EU-EC-10010579793 | | 2021-11-08 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7835 | click or scan EU-EC-10010579775 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7836 | click or scan EU-EC-10010578870 | | 2021-11-08 | Healthcare Professional | EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7837 | click or scan EU-EC-10010578870 | | 2021-11-08 | Healthcare Professional | EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7838 | click or scan EU-EC-10010578847 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 7839 | click or scan EU-EC-10010578832 | | 2021-11-08 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7840 | click or scan EU-EC-10010578392 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Hypotonia (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 7841 | click or scan EU-EC-10010577416 | | 2021-11-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Coronary artery embolism (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7842 | click or scan EU-EC-10010577231 | | 2021-11-08 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 7843 | click or scan EU-EC-10010577229 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Female | Amylase increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Blood glucose increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interleukin level increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rales (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sinus tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7844 | click or scan EU-EC-10010576849 | | 2021-11-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7845 | click or scan EU-EC-10010576736 | | 2021-11-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Bronchospasm (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - ), Sneezing (n/a - Unknown - ), Subdural haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Weaning failure (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) |
| 7846 | click or scan EU-EC-10010576674 | | 2021-11-08 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 7847 | click or scan EU-EC-10010576633 | | 2021-11-08 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhagic stroke (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7848 | click or scan EU-EC-10010576070 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 7849 | click or scan EU-EC-10010576006 | | 2021-11-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Agranulocytosis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (2d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (2d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (2d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Immunosuppression (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Soft tissue infection (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (2d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100ug - Intramuscular]) |
| 7850 | click or scan EU-EC-10010575982 | | 2021-11-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7851 | click or scan EU-EC-10010575946 | | 2021-11-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (24d - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic respiratory failure (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Decubitus ulcer (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Hypercapnia (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Mental status changes (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7852 | click or scan EU-EC-10010575675 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - Other Medically Important Condition), Constipation (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Urinary retention (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7853 | click or scan EU-EC-10010575609 | | 2021-11-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7854 | click or scan EU-EC-10010574592 | | 2021-11-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7855 | click or scan EU-EC-10010572230 | | 2021-11-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (0d - Fatal - **Results in Death**), Headache (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 7856 | click or scan EU-EC-10010572203 | | 2021-11-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7857** | click or scan EU-EC-10010572068 |  | 2021-11-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | CSF glucose abnormal (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **7858** | click or scan EU-EC-10010572032 |  | 2021-11-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Coma (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **7859** | click or scan EU-EC-10010571201 |  | 2021-11-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7860** | click or scan EU-EC-10010571175 |  | 2021-11-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Respiratory distress (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **7861** | click or scan EU-EC-10010570033 |  | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **7862** | click or scan EU-EC-10010569948 |  | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular - More in ICSR]) |
| **7863** | click or scan EU-EC-10010569652 |  | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **7864** | click or scan EU-EC-10010569604 |  | 2021-11-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Autoimmune hepatitis (68d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7865** | click or scan EU-EC-10010569539 |  | 2021-11-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7866** | click or scan EU-EC-10010569511 |  | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7867 | click or scan EU-EC-10010569421 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7868 | click or scan EU-EC-10010569073 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7869 | click or scan EU-EC-10010569046 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown - More in ICSR]) |
| 7870 | click or scan EU-EC-10010569011 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7871 | click or scan EU-EC-10010568828 | | 2021-11-05 | Non Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7872 | click or scan EU-EC-10010568738 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7873 | click or scan EU-EC-10010568553 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7874 | click or scan EU-EC-10010568040 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7875 | click or scan EU-EC-10010567944 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7876 | click or scan EU-EC-10010567855 | | 2021-11-05 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7877 | click or scan EU-EC-10010567837 | | 2021-11-05 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7878 | click or scan EU-EC-10010567835 | | 2021-11-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Back pain (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 7879 | click or scan EU-EC-10010567832 | | 2021-11-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 7880 | click or scan EU-EC-10010567827 | | 2021-11-05 | Healthcare Professional | EEA | More than 85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Gastrointestinal ulcer (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 7881 | click or scan EU-EC-10010567639 | | 2021-11-05 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 7882 | click or scan EU-EC-10010567606 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7883 | click or scan EU-EC-10010567490 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7884 | click or scan EU-EC-10010567420 | | 2021-11-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 7885 | click or scan EU-EC-10010567397 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (4d - Fatal - **Results in Death**), Headache (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 7886 | click or scan EU-EC-10010567311 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Idiopathic pulmonary fibrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary tuberculosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Rhinorrhoea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7887** | click or scan EU-EC-10010567213 | | 2021-11-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Immobile (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Limb injury (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **7888** | click or scan EU-EC-10010567104 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (12d - Fatal - **Results in Death**), Dizziness (13d - Fatal - **Results in Death**), Fatigue (12d - Fatal - **Results in Death**), Hepatitis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Impaired work ability (235h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (12d - Fatal - **Results in Death**), Pyrexia (238h - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7889** | click or scan EU-EC-10010567002 | | 2021-11-05 | Healthcare Professional | EEA | 65-85 Years | Female | Foetal cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **7890** | click or scan EU-EC-10010566767 | | 2021-11-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **7891** | click or scan EU-EC-10010566635 | | 2021-11-05 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **7892** | click or scan EU-EC-10010566634 | | 2021-11-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Increased upper airway secretion (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rales (n/a - Fatal - **Results in Death**), Rash macular (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory tract haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **7893** | click or scan EU-EC-10010566632 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ), Pericardial effusion (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7894** | click or scan EU-EC-10010566573 | | 2021-11-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Fluid intake reduced (n/a - Unknown - ), Hypokinesia (n/a - Unknown - ), Mouth breathing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **7895** | click or scan EU-EC-10010566191 | | 2021-11-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **7896** | click or scan EU-EC-10010566187 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ), Productive cough (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7897** | click or scan EU-EC-10010565519 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7898** | click or scan EU-EC-10010565481 | | 2021-11-05 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Atrial septal defect (n/a - Fatal - **Results in Death**), Atrioventricular septal defect (n/a - Fatal - **Results in Death**), Hypoplastic left heart syndrome (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]), [SERTRALINE HYDROCHLORIDE] (S - Anxiety - Dose not changed - [n/a - 50mg - Transplacental]) |
| **7899** | click or scan EU-EC-10010565477 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7900** | click or scan EU-EC-10010565398 | | 2021-11-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Capillary nail refill test abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Use of accessory respiratory muscles (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7901** | click or scan EU-EC-10010565190 | | 2021-11-05 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **7902** | click or scan EU-EC-10010564711 | | 2021-11-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acidosis (1d - Fatal - **Results in Death**), Anuria (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7903 | click or scan EU-EC-10010564265 | | 2021-11-05 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain death (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Incarcerated hernia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pupils unequal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) |
| 7904 | click or scan EU-EC-10010563684 | | 2021-11-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (1s - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 7905 | click or scan EU-EC-10010563341 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Myocardial rupture (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 7906 | click or scan EU-EC-10010563333 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7907 | click or scan EU-EC-10010563324 | | 2021-11-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7908 | click or scan EU-EC-10010563320 | | 2021-11-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Cognitive disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7909 | click or scan EU-EC-10010563317 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Unknown - ), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7910 | click or scan EU-EC-10010563174 | | 2021-11-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cervix carcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7911 | click or scan EU-EC-10010563014 | | 2021-11-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**), Hemiplegia (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 7912 | click or scan EU-EC-10010562905 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Recovering/Resolving - ), Back pain (n/a - Recovering/Resolving - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Neck pain (n/a - Recovering/Resolving - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 7913 | click or scan EU-EC-10010562814 | | 2021-11-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure chronic (0d - Fatal - **Results in Death**), Hypertension (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 7914 | click or scan EU-EC-10010562796 | | 2021-11-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Cardiogenic shock (n/a - Unknown - Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**), Tricuspid valve disease (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 7915 | click or scan EU-EC-10010562711 | | 2021-11-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Atrioventricular block (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 7916 | click or scan EU-EC-10010562515 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Insomnia (n/a - Unknown - Caused/Prolonged Hospitalisation), Skin discolouration (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7917 | click or scan EU-EC-10010562485 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac discomfort (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7918 | click or scan EU-EC-10010562459 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (25d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (25d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (25d - Fatal - **Results in Death**, Other Medically Important Condition), Post cardiac arrest syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sense of oppression (25d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7919 | click or scan EU-EC-10010562451 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (11d - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7920 | click or scan EU-EC-10010562371 | | 2021-11-05 | Non Healthcare Professional | Non EEA | Not Specified | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7921 | click or scan EU-EC-10010562331 | | 2021-11-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7922 | click or scan EU-EC-10010562167 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Injury (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 7923 | click or scan EU-EC-10010562150 | | 2021-11-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7924 | click or scan EU-EC-10010561926 | | 2021-11-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7925 | click or scan EU-EC-10010561804 | | 2021-11-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 7926 | click or scan EU-EC-10010561796 | | 2021-11-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7927 | click or scan EU-EC-10010561548 | | 2021-11-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 7928 | click or scan EU-EC-10010561528 | | 2021-11-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Haemorrhage intracranial (n/a - Unknown - Life Threatening, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 7929 | click or scan EU-EC-10010560566 | | 2021-11-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage foetal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 7930 | click or scan EU-EC-10010559099 | | 2021-11-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 7931 | click or scan EU-EC-10010559032 | | 2021-11-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7932 | click or scan EU-EC-10010558873 | | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism venous (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nucleic acid test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombectomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound Doppler (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 7933 | click or scan EU-EC-10010558488 | | 2021-11-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Basilar artery thrombosis (n/a - Unknown - Other Medically Important Condition), Peripheral arterial occlusive disease (n/a - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7934 | click or scan EU-EC-10010558486 | | 2021-11-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7935 | click or scan EU-EC-10010558477 | | 2021-11-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7936 | click or scan EU-EC-10010558459 | | 2021-11-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Hepatitis (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Rash (24d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7937 | click or scan EU-EC-10010558449 | | 2021-11-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7938 | click or scan EU-EC-10010558231 | | 2021-11-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fungal infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 7939 | click or scan EU-EC-10010557802 | | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dilatation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7940** | click or scan EU-EC-10010557372 | | 2021-11-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Bone marrow failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **7941** | click or scan EU-EC-10010557186 | | 2021-11-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Swelling face (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **7942** | click or scan EU-EC-10010556969 | | 2021-11-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **7943** | click or scan EU-EC-10010556834 | | 2021-11-04 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Anomalous pulmonary venous connection (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Atrial septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Congenital great vessel anomaly (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Death neonatal (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly), Heterotaxia (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Multiple congenital abnormalities (n/a - Unknown - Congenital Anomaly), Ventricular hypoplasia (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **7944** | click or scan EU-EC-10010553989 | | 2021-11-04 | Healthcare Professional | EEA | 18-64 Years | Male | Brain injury (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **7945** | click or scan EU-EC-10010553987 | | 2021-11-04 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| **7946** | click or scan EU-EC-10010553799 | | 2021-11-04 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **7947** | click or scan EU-EC-10010553264 | | 2021-11-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7948** | click or scan EU-EC-10010552675 | | 2021-11-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **7949** | click or scan EU-EC-10010552516 | | 2021-11-04 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Respiratory failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7950 | click or scan EU-EC-10010552265 |  | 2021-11-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| 7951 | click or scan EU-EC-10010552153 |  | 2021-11-04 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cor pulmonale (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung abscess (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (3mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7952 | click or scan EU-EC-10010552142 |  | 2021-11-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Atrial fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hydrocephalus (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Intraventricular haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Lethargy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 7953 | click or scan EU-EC-10010552101 |  | 2021-11-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7954 | click or scan EU-EC-10010551771 |  | 2021-11-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7955 | click or scan EU-EC-10010551661 |  | 2021-11-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 7956 | click or scan EU-EC-10010551643 |  | 2021-11-04 | Healthcare Professional | EEA | More than 85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 7957 | click or scan EU-EC-10010551454 |  | 2021-11-04 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (2d - Fatal - **Results in Death**), Coronavirus test positive (7d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Skin haemorrhage (2d - Fatal - **Results in Death**), Somnolence (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 7958 | click or scan EU-EC-10010551421 |  | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **7959** | click or scan EU-EC-10010551403 | | 2021-11-04 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **7960** | click or scan EU-EC-10010551208 | | 2021-11-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (11d - Fatal - **Results in Death**), Chills (11d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (11d - Fatal - **Results in Death**), Hyperhidrosis (11d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (11d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **7961** | click or scan EU-EC-10010550689 | | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ascites (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic hepatitis C (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (47d - Unknown - ), Fatigue (47d - Unknown - ), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung opacity (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Thrombocytopenia (6d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **7962** | click or scan EU-EC-10010550545 | | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Hypersomnia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **7963** | click or scan EU-EC-10010550409 | | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **7964** | click or scan EU-EC-10010550166 | | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**), Histamine level increased (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Tryptase increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **7965** | click or scan EU-EC-10010550122 | | 2021-11-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cyanosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling hot (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paranasal sinus discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **7966** | click or scan EU-EC-10010549971 |  | 2021-11-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Areflexia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pupil fixed (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **7967** | click or scan EU-EC-10010549874 |  | 2021-11-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysstasia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eye movement disorder (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding disorder (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza like illness (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injected limb mobility decreased (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasticity (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **7968** | click or scan EU-EC-10010548239 |  | 2021-11-03 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **7969** | click or scan EU-EC-10010547748 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **7970** | click or scan EU-EC-10010547747 |  | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **7971** | click or scan EU-EC-10010547579 |  | 2021-11-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **7972** | click or scan EU-EC-10010547404 |  | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Agitation (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Idiopathic pulmonary fibrosis (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7973 | click or scan EU-EC-10010547168 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 7974 | click or scan EU-EC-10010547001 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic sinusitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7975 | click or scan EU-EC-10010546997 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7976 | click or scan EU-EC-10010546986 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain compression (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebellar stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral mass effect (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lateral medullary syndrome (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertebral artery occlusion (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7977 | click or scan EU-EC-10010546728 | | 2021-11-03 | Healthcare Professional | EEA | 18-64 Years | Male | Delirium (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Unknown - ), Myalgia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7978 | click or scan EU-EC-10010546711 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7979 | click or scan EU-EC-10010546505 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Recovering/Resolving - ), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7980 | click or scan EU-EC-10010546323 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain upper (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7981 | click or scan EU-EC-10010546127 | | 2021-11-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Exposure during pregnancy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 7982 | click or scan EU-EC-10010545684 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic stenosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7983 | click or scan EU-EC-10010545588 | | 2021-11-03 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [34d - 2 {DF} - Intramuscular]) |
| 7984 | click or scan EU-EC-10010545521 | | 2021-11-03 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7985 | click or scan EU-EC-10010545511 | | 2021-11-03 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (40d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7986 | click or scan EU-EC-10010545504 | | 2021-11-03 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 7987 | click or scan EU-EC-10010545182 | | 2021-11-03 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Paresis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paresis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 7988 | click or scan EU-EC-10010544470 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Ocular hyperaemia (n/a - Unknown - ), Purpura (n/a - Unknown - ), Upper respiratory tract congestion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7989 | click or scan EU-EC-10010544357 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Condition aggravated (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7990 | click or scan EU-EC-10010544077 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7991 | click or scan EU-EC-10010543986 | | 2021-11-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pericarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7992 | click or scan EU-EC-10010543735 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaemia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism arterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epistaxis (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Melaena (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mucosal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper airway obstruction (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7993 | click or scan EU-EC-10010543570 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 7994 | click or scan EU-EC-10010543421 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Balance disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Basal ganglia haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coordination abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Impaired driving ability (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7995 | click or scan EU-EC-10010542850 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mobility decreased (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 7996 | click or scan EU-EC-10010542750 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (5d - Fatal - **Results in Death**), Feeling hot (5d - Fatal - **Results in Death**), Headache (5d - Fatal - **Results in Death**), Influenza like illness (n/a - Recovered/Resolved - ), Nausea (5d - Fatal - **Results in Death**), Peripheral swelling (5d - Fatal - **Results in Death**), Vomiting (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 7997 | click or scan EU-EC-10010542569 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperlipidaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 7998 | click or scan EU-EC-10010542517 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 7999 | click or scan EU-EC-10010542499 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8000 | click or scan EU-EC-10010542492 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiomegaly (n/a - Unknown - ), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - ), Renal failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8001 | click or scan EU-EC-10010542487 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arthralgia (n/a - Unknown - ), Dyspnoea (1h - Recovered/Resolved - ), Interstitial lung disease (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8002 | click or scan EU-EC-10010542483 | | 2021-11-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Decapitation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8003 | click or scan EU-EC-10010542481 | | 2021-11-03 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Atrial flutter (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Carotid arteriosclerosis (n/a - Unknown - Other Medically Important Condition), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Hypoxia (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8004 | click or scan EU-EC-10010542474 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8005 | click or scan EU-EC-10010542472 | | 2021-11-03 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8006 | click or scan EU-EC-10010542455 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cholelithiasis (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Gallbladder oedema (n/a - Unknown - Other Medically Important Condition), Movement disorder (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Sinusitis (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8007 | click or scan EU-EC-10010542447 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haematuria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemorrhage subcutaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic diathesis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8008 | click or scan EU-EC-10010542425 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8009 | click or scan EU-EC-10010542416 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8010 | click or scan EU-EC-10010542414 | | 2021-11-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8011 | click or scan EU-EC-10010542370 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8012 | click or scan EU-EC-10010542252 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8013 | click or scan EU-EC-10010542220 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Vaccination error (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8014 | click or scan EU-EC-10010542200 | | 2021-11-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8015 | click or scan EU-EC-10010542151 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8016 | click or scan EU-EC-10010541980 | | 2021-11-03 | Non Healthcare Professional | EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8017 | click or scan EU-EC-10010541714 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8018 | click or scan EU-EC-10010541675 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cholecystitis acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 8019 | click or scan EU-EC-10010541561 | | 2021-11-03 | Healthcare Professional | EEA | 65-85 Years | Male | Foreign body in respiratory tract (n/a - Fatal - **Results in Death**), Giant cell arteritis (n/a - Fatal - **Results in Death**), Lymphocytic infiltration (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8020 | click or scan EU-EC-10010541542 | | 2021-11-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8021 | click or scan EU-EC-10010541478 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [INFLUENZA A VIRUS A/TEXAS/50/2012 X-223A (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA A VIRUS A/CALIFORNIA/7/2009 X-179A (H1N1) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA B VIRUS B/MASSACHUSETTS/2/2012 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA B VIRUS B/BRISBANE/60/2008 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)] (S - Product used for unknown indication - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8022 | click or scan EU-EC-10010541201 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8023 | click or scan EU-EC-10010541185 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8024 | click or scan EU-EC-10010541054 | | 2021-11-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Not Recovered/Not Resolved - ), Body temperature increased (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Recovered/Resolved - ), Condition aggravated (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site erythema (n/a - Not Recovered/Not Resolved - ), Injection site inflammation (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Not Recovered/Not Resolved - ), Injection site warmth (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myalgia (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 8025 | click or scan EU-EC-10010541028 | | 2021-11-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Haematoma (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nasal dryness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 8026 | click or scan EU-EC-10010540947 | | 2021-11-03 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8027 | click or scan EU-EC-10010540909 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8028 | click or scan EU-EC-10010540895 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8029 | click or scan EU-EC-10010540823 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchial carcinoma (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8030 | click or scan EU-EC-10010540797 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (24d - Unknown - Caused/Prolonged Hospitalisation), Cough (24d - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (24d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (24d - Unknown - Caused/Prolonged Hospitalisation), Pain (24d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (24d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (24d - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (24d - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8031 | click or scan EU-EC-10010540761 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8032 | click or scan EU-EC-10010540529 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8033 | click or scan EU-EC-10010540006 |  | 2021-11-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Generalised oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 8034 | click or scan EU-EC-10010539902 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8035 | click or scan EU-EC-10010539592 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8036 | click or scan EU-EC-10010539565 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8037 | click or scan EU-EC-10010539564 |  | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Conjunctival hyperaemia (14d - Fatal - **Results in Death**), Malaise (14d - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (14d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8038 | click or scan EU-EC-10010539456 |  | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8039 | click or scan EU-EC-10010539433 |  | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8040 | click or scan EU-EC-10010539413 |  | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hepatic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ), Vaccination site reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8041 | click or scan EU-EC-10010539334 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8042 | click or scan EU-EC-10010539327 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8043 | click or scan EU-EC-10010539270 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8044 | click or scan EU-EC-10010539237 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8045 | click or scan EU-EC-10010539235 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysstasia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Head injury (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rib fracture (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8046 | click or scan EU-EC-10010539195 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8047 | click or scan EU-EC-10010539176 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8048 | click or scan EU-EC-10010539122 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiosarcoma (39d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (39d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Photophobia (39d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vertigo (39d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (39d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8049 | click or scan EU-EC-10010539070 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8050 | click or scan EU-EC-10010539060 | | 2021-11-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8051 | click or scan EU-EC-10010538984 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8052 | click or scan EU-EC-10010538831 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8053 | click or scan EU-EC-10010538637 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8054 | click or scan EU-EC-10010538577 | | 2021-11-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyslexia (n/a - Unknown - Other Medically Important Condition), Intellectual disability (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition), Mental disorder (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Retinal degeneration (n/a - Unknown - Other Medically Important Condition), Retinal detachment (n/a - Unknown - Other Medically Important Condition), Retinal tear (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8055 | click or scan EU-EC-10010538577 | | 2021-11-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyslexia (n/a - Unknown - Other Medically Important Condition), Intellectual disability (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition), Mental disorder (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Retinal degeneration (n/a - Unknown - Other Medically Important Condition), Retinal detachment (n/a - Unknown - Other Medically Important Condition), Retinal tear (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8056 | click or scan EU-EC-10010538337 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8057 | click or scan EU-EC-10010538315 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Unknown - ), Injury (1d - Unknown - ), Loss of consciousness (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8058 | click or scan EU-EC-10010538307 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epistaxis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8059 | click or scan EU-EC-10010538248 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8060 | click or scan EU-EC-10010538217 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute hepatic failure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8061 | click or scan EU-EC-10010538204 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrolyte imbalance (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Livedo reticularis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral ischaemia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia bacterial (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8062 | click or scan EU-EC-10010538187 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8063 | click or scan EU-EC-10010538169 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8064 | click or scan EU-EC-10010538059 | | 2021-11-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8065 | click or scan EU-EC-10010538046 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cholelithiasis (n/a - Fatal - **Results in Death**), Coma scale abnormal (n/a - Fatal - **Results in Death**), Diverticulum intestinal (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Fatal - **Results in Death**), Fibrinolysis increased (n/a - Fatal - **Results in Death**), Haematochezia (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Intestinal dilatation (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8066 | click or scan EU-EC-10010538004 | | 2021-11-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8067 | click or scan EU-EC-10010537979 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8068 | click or scan EU-EC-10010537969 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8069 | click or scan EU-EC-10010537960 |  | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anal incontinence (n/a - Unknown - Other Medically Important Condition), Anxiety (n/a - Unknown - Other Medically Important Condition), Bedridden (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Grimacing (n/a - Unknown - Other Medically Important Condition), Moaning (n/a - Unknown - Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**), Painful respiration (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Perineal pain (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Vaginal discharge (n/a - Fatal - **Results in Death**), Vaginal fistula (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8070 | click or scan EU-EC-10010537897 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8071 | click or scan EU-EC-10010537896 |  | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8072 | click or scan EU-EC-10010537855 |  | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiopulmonary failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8073 | click or scan EU-EC-10010537842 |  | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory tract congestion (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8074 | click or scan EU-EC-10010537812 |  | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetes mellitus inadequate control (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 8075 | click or scan EU-EC-10010537805 |  | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8076 | click or scan EU-EC-10010537798 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis (4d - Fatal - **Results in Death**), Condition aggravated (4d - Fatal - **Results in Death**), Diabetes mellitus (4d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8077 | click or scan EU-EC-10010537710 |  | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (1d - Fatal - **Results in Death**), Disorientation (1d - Fatal - **Results in Death**), Dyspnoea (8d - Fatal - **Results in Death**), Feeling abnormal (8d - Fatal - **Results in Death**), Gait disturbance (1d - Fatal - **Results in Death**), Influenza like illness (8d - Fatal - **Results in Death**), Pain (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8078 | click or scan EU-EC-10010537665 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8079 | click or scan EU-EC-10010537652 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8080 | click or scan EU-EC-10010537621 | | 2021-11-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal hernia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysstasia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vein collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8081 | click or scan EU-EC-10010537588 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia bacterial (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8082 | click or scan EU-EC-10010537490 | | 2021-11-03 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cleft lip and palate (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Congenital eye disorder (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Dysmorphism (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Foetal damage (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 8083 | click or scan EU-EC-10010537457 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic obstructive pulmonary disease (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary fibrosis (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8084 | click or scan EU-EC-10010537382 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8085 | click or scan EU-EC-10010537336 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8086 | click or scan EU-EC-10010537085 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8087 | click or scan EU-EC-10010537048 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8088 | click or scan EU-EC-10010536847 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Neutrophil count increased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8089 | click or scan EU-EC-10010536838 | | 2021-11-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Epistaxis (n/a - Unknown - Other Medically Important Condition), Hyperpyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8090 | click or scan EU-EC-10010536773 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pulmonary fibrosis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8091 | click or scan EU-EC-10010536752 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8092 | click or scan EU-EC-10010536714 | | 2021-11-03 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 8093 | click or scan EU-EC-10010536617 | | 2021-11-03 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Haemorrhoids (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8094 | click or scan EU-EC-10010536608 | | 2021-11-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8095 | click or scan EU-EC-10010535819 | | 2021-11-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (129d - Fatal - **Results in Death**), Hypertonia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Memory impairment (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8096 | click or scan EU-EC-10010535818 | | 2021-11-02 | Non Healthcare Professional | EEA | More than 85 Years | Male | Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8097 | click or scan EU-EC-10010535776 | | 2021-11-02 | Non Healthcare Professional | EEA | Not Specified | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Ascites (n/a - Fatal - **Results in Death**), Chills (150d - Fatal - **Results in Death**), Chills (151d - Fatal - **Results in Death**), Dyspnoea (115d - Fatal - **Results in Death**), Lymphadenopathy (84d - Fatal - **Results in Death**), Malaise (115d - Fatal - **Results in Death**), Nausea (151d - Fatal - **Results in Death**), Tachycardia (115d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8098 | click or scan EU-EC-10010535709 | | 2021-11-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Tachycardia (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8099 | click or scan EU-EC-10010535561 | | 2021-11-02 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 8100 | click or scan EU-EC-10010532592 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Not Specified | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8101 | click or scan EU-EC-10010532346 | | 2021-11-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8102 | click or scan EU-EC-10010532275 | | 2021-11-02 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 8103 | click or scan EU-EC-10010532267 | | 2021-11-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8104 | click or scan EU-EC-10010532260 | | 2021-11-02 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8105 | click or scan EU-EC-10010532214 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8106 | click or scan EU-EC-10010531231 | | 2021-11-02 | Healthcare Professional | EEA | Not Specified | Not Specified | Congenital central nervous system anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Unknown - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental]) |
| 8107 | click or scan EU-EC-10010529907 | | 2021-11-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8108 | click or scan EU-EC-10010529080 | | 2021-11-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Vaccination site pain (n/a - Fatal - **Results in Death**), Vaccination site swelling (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8109 | click or scan EU-EC-10010527883 | | 2021-11-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Encephalomyelitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Unknown - Life Threatening), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8110 | click or scan EU-EC-10010527878 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8111 | click or scan EU-EC-10010526326 | | 2021-11-02 | Healthcare Professional | EEA | More than 85 Years | Male | Chills (4d - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Vomiting (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 8112 | click or scan EU-EC-10010524673 | | 2021-11-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (2min - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [6mo - .3mL - Intramuscular]) |
| 8113 | click or scan EU-EC-10010524413 | | 2021-11-02 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8114 | click or scan EU-EC-10010524354 | | 2021-11-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pyrexia (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8115 | click or scan EU-EC-10010524211 | | 2021-11-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8116 | click or scan EU-EC-10010522153 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8117 | click or scan EU-EC-10010522142 | | 2021-11-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8118 | click or scan EU-EC-10010520854 |  | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 8119 | click or scan EU-EC-10010520819 |  | 2021-11-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8120 | click or scan EU-EC-10010520212 |  | 2021-11-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Ejection fraction decreased (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), PO2 decreased (n/a - Fatal - **Results in Death**), Percutaneous coronary intervention (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Thrombectomy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8121 | click or scan EU-EC-10010519806 |  | 2021-11-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8122 | click or scan EU-EC-10010519607 |  | 2021-11-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8123 | click or scan EU-EC-10010519597 |  | 2021-11-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8124 | click or scan EU-EC-10010519394 |  | 2021-11-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8125 | click or scan EU-EC-10010517896 |  | 2021-11-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Herpes zoster meningoencephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8126 | click or scan EU-EC-10010517892 |  | 2021-11-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 8127 | click or scan EU-EC-10010517855 |  | 2021-11-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocarditis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8128 | click or scan EU-EC-10010517266 |  | 2021-11-02 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 8129 | click or scan EU-EC-10010517244 |  | 2021-11-02 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Pain (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 8130 | click or scan EU-EC-10010516675 |  | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8131 | click or scan EU-EC-10010515992 |  | 2021-11-02 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 8132 | click or scan EU-EC-10010515792 |  | 2021-11-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Neoplasm progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8133 | click or scan EU-EC-10010515417 |  | 2021-11-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8134 | click or scan EU-EC-10010515398 |  | 2021-11-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Amenorrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Blood test abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Hepatic failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatomegaly (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Jaundice (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ocular icterus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Yellow skin (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8135 | click or scan EU-EC-10010515317 |  | 2021-11-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8136 | click or scan EU-EC-10010514611 |  | 2021-11-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiopulmonary failure (1d - Fatal - **Results in Death**), Diabetes mellitus (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8137 | click or scan EU-EC-10010513910 | | 2021-11-02 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Death (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8138 | click or scan EU-EC-10010513292 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Secretion discharge (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8139 | click or scan EU-EC-10010512646 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Male | Infection (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8140 | click or scan EU-EC-10010510370 | | 2021-11-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysstasia (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8141 | click or scan EU-EC-10010510272 | | 2021-11-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8142 | click or scan EU-EC-10010510171 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (1wk - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8143 | click or scan EU-EC-10010510150 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular arrhythmia (2d - Fatal - **Results in Death**), Ventricular tachycardia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8144 | click or scan EU-EC-10010510149 | | 2021-11-02 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (2wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8145 | click or scan EU-EC-10010510097 | | 2021-11-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (n/a - Unknown - ), Headache (2d - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8146 | click or scan EU-EC-10010509774 | | 2021-11-02 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal renal impairment (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Renal aplasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8147 | click or scan EU-EC-10010508832 | | 2021-11-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory depression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8148 | click or scan EU-EC-10010508324 | | 2021-11-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8149 | click or scan EU-EC-10010508145 | | 2021-11-02 | Healthcare Professional | Non EEA | Not Specified | Female | Stillbirth (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8150 | click or scan EU-EC-10010507966 | | 2021-11-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Amnesia (88d - Fatal - **Results in Death**), Fatigue (88d - Fatal - **Results in Death**), Haemorrhagic stroke (88d - Fatal - **Results in Death**), Pain in extremity (88d - Fatal - **Results in Death**), Paraesthesia (88d - Fatal - **Results in Death**), Vascular pain (88d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8151 | click or scan EU-EC-10010507945 | | 2021-11-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (66d - Fatal - **Results in Death**), Pneumonia (66d - Fatal - **Results in Death**), Thrombosis (66d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 8152 | click or scan EU-EC-10010507942 | | 2021-11-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (12d - Fatal - **Results in Death**), Aortic aneurysm (12d - Fatal - **Results in Death**), Arterial thrombosis (12d - Fatal - **Results in Death**), Gastrointestinal necrosis (12d - Fatal - **Results in Death**), Oedema peripheral (12d - Fatal - **Results in Death**), Rectal haemorrhage (12d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8153 | click or scan EU-EC-10010507669 | | 2021-11-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dermatitis bullous (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Unknown - ), Lip discolouration (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ), Pruritus (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8154 | click or scan EU-EC-10010507582 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8155 | click or scan EU-EC-10010507480 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemoptysis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8156 | click or scan EU-EC-10010507478 | | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8157 | click or scan EU-EC-10010507462 | | 2021-11-01 | Healthcare Professional | Non EEA | Not Specified | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Irritability postvaccinal (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8158 | click or scan EU-EC-10010507460 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8159 | click or scan EU-EC-10010507457 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8160 | click or scan EU-EC-10010507456 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8161 | click or scan EU-EC-10010507445 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8162 | click or scan EU-EC-10010507440 |  | 2021-11-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8163 | click or scan EU-EC-10010507430 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8164 | click or scan EU-EC-10010507424 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8165 | click or scan EU-EC-10010507417 |  | 2021-11-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8166 | click or scan EU-EC-10010507383 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8167 | click or scan EU-EC-10010507377 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8168 | click or scan EU-EC-10010507342 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8169 | click or scan EU-EC-10010507325 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8170 | click or scan EU-EC-10010507268 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8171 | click or scan EU-EC-10010507248 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8172 | click or scan EU-EC-10010507195 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8173 | click or scan EU-EC-10010507192 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8174 | click or scan EU-EC-10010507191 |  | 2021-11-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8175 | click or scan EU-EC-10010506885 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anti-platelet factor 4 antibody positive (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Brain herniation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hydrocephalus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Transverse sinus thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8176 | click or scan EU-EC-10010506792 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8177 | click or scan EU-EC-10010506711 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8178 | click or scan EU-EC-10010506665 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8179 | click or scan EU-EC-10010506659 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8180 | click or scan EU-EC-10010506622 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8181 | click or scan EU-EC-10010506611 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8182 | click or scan EU-EC-10010506603 |  | 2021-11-01 | Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8183 | click or scan EU-EC-10010506598 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8184 | click or scan EU-EC-10010506597 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8185 | click or scan EU-EC-10010506594 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8186 | click or scan EU-EC-10010506578 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8187 | click or scan EU-EC-10010506577 |  | 2021-11-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8188 | click or scan EU-EC-10010506572 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **8189** | click or scan EU-EC-10010506484 | | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **8190** | click or scan EU-EC-10010506470 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Anuria (n/a - Unknown - Other Medically Important Condition), Arterial thrombosis (n/a - Fatal - **Results in Death**), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood urine present (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Cholestasis (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dehydration (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Faeces discoloured (n/a - Unknown - ), Haematemesis (n/a - Unknown - Other Medically Important Condition), Haematochezia (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Hypoperfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - ), Intra-abdominal haemorrhage (n/a - Unknown - Other Medically Important Condition), Jaundice (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pneumatosis intestinalis (n/a - Unknown - Other Medically Important Condition), Portal hypertension (n/a - Unknown - ), Portal hypertensive gastropathy (n/a - Unknown - ), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Tremor (n/a - Unknown - ), Vaginal haemorrhage (n/a - Unknown - ), Varices oesophageal (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **8191** | click or scan EU-EC-10010506284 | | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (132d - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Hyponatraemia (n/a - Unknown - Other Medically Important Condition), Left ventricular dysfunction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **8192** | click or scan EU-EC-10010506019 | | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **8193** | click or scan EU-EC-10010505944 | | 2021-11-01 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **8194** | click or scan EU-EC-10010505770 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disorientation (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8195 | click or scan EU-EC-10010505501 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardioversion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Extubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Laboratory test normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Prone position (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vasopressive therapy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8196 | click or scan EU-EC-10010505498 | | 2021-11-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8197 | click or scan EU-EC-10010505429 | | 2021-11-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 5mL - Intramuscular]) |
| 8198 | click or scan EU-EC-10010505410 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Nuchal rigidity (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8199 | click or scan EU-EC-10010505406 | | 2021-11-01 | Healthcare Professional | EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8200 | click or scan EU-EC-10010505402 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8201 | click or scan EU-EC-10010505367 | | 2021-11-01 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8202 | click or scan EU-EC-10010505204 | | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cognitive disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Eating disorder (n/a - Unknown - ), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8203 | click or scan EU-EC-10010504719 |  | 2021-11-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8204 | click or scan EU-EC-10010504655 |  | 2021-11-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8205 | click or scan EU-EC-10010503675 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Emphysema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Silicosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8206 | click or scan EU-EC-10010503671 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8207 | click or scan EU-EC-10010503665 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8208 | click or scan EU-EC-10010503633 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8209 | click or scan EU-EC-10010503513 |  | 2021-11-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Blood glucose increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysstasia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hunger (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8210 | click or scan EU-EC-10010503451 |  | 2021-11-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8211 | click or scan EU-EC-10010503447 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Crepitations (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Puncture site bruise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rales (n/a - Fatal - **Results in Death**), Rhonchi (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8212 | click or scan EU-EC-10010503115 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8213 | click or scan EU-EC-10010502646 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8214 | click or scan EU-EC-10010502629 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8215 | click or scan EU-EC-10010501988 |  | 2021-11-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Leg amputation (n/a - Unknown - Life Threatening, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8216 | click or scan EU-EC-10010501987 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8217 | click or scan EU-EC-10010501985 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypopnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Sleep paralysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8218 | click or scan EU-EC-10010501781 |  | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8219 | click or scan EU-EC-10010501628 |  | 2021-11-01 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac dysfunction (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8220 | click or scan EU-EC-10010501619 |  | 2021-11-01 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (69d - Fatal - **Results in Death**), Pleural effusion (69d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 8221 | click or scan EU-EC-10010501597 |  | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8222 | click or scan EU-EC-10010501193 |  | 2021-11-01 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**), Drug ineffective (2d - Fatal - **Results in Death**), Vaccination failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8223 | click or scan EU-EC-10010500983 | | 2021-11-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**, Life Threatening), Malignant neoplasm of renal pelvis (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8224 | click or scan EU-EC-10010500904 | | 2021-11-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8225 | click or scan EU-EC-10010500705 | | 2021-11-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8226 | click or scan EU-EC-10010499184 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8227 | click or scan EU-EC-10010499045 | | 2021-11-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8228 | click or scan EU-EC-10010498900 | | 2021-11-01 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [ETHINYLESTRADIOL, ETONOGESTREL] (S - Contraception - Not applicable - [n/a - n/a - n/a]) |
| 8229 | click or scan EU-EC-10010498657 | | 2021-11-01 | Healthcare Professional | EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Acute myocardial infarction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Aphasia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Blood pressure increased (n/a - Unknown - Life Threatening, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Brain oedema (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Life Threatening, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Coma (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Demyelination (n/a - Unknown - Life Threatening, Other Medically Important Condition), Haematoma (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypertensive crisis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Life Threatening, Other Medically Important Condition), Pyramidal tract syndrome (n/a - Unknown - Life Threatening, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Troponin increased (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8230 | click or scan EU-EC-10010498278 | | 2021-10-31 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (1mo - Fatal - **Results in Death**), Sepsis (1mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8231 | click or scan EU-EC-10010498246 | | 2021-10-31 | Healthcare Professional | EEA | 65-85 Years | Female | Altered state of consciousness (0d - Fatal - **Results in Death**), Body temperature increased (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Hyperhidrosis (0d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8232 | click or scan EU-EC-10010498195 | | 2021-10-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cytokine storm (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8233 | click or scan EU-EC-10010498165 | | 2021-10-31 | Healthcare Professional | EEA | 65-85 Years | Female | Sepsis (1wk - Fatal - **Results in Death**), Urosepsis (1wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8234 | click or scan EU-EC-10010498134 | | 2021-10-31 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (2wk - Fatal - **Results in Death**), Sepsis (2wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8235 | click or scan EU-EC-10010497254 | | 2021-10-30 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (2wk - Fatal - **Results in Death**), Sepsis (2wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8236 | click or scan EU-EC-10010497147 | | 2021-10-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8237 | click or scan EU-EC-10010497143 | | 2021-10-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypopnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular - More in ICSR]) |
| 8238 | click or scan EU-EC-10010495922 | | 2021-10-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ataxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Medication error (n/a - Unknown - ), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8239 | click or scan EU-EC-10010495268 | | 2021-10-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Amnesia (178d - Fatal - **Results in Death**), Areflexia (178d - Fatal - **Results in Death**), Asthenia (178d - Fatal - **Results in Death**), Condition aggravated (178d - Fatal - **Results in Death**), Loss of consciousness (178d - Fatal - **Results in Death**), Seizure (178d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - Intramuscular]) |
| 8240 | click or scan EU-EC-10010495015 | | 2021-10-30 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (102d - Fatal - **Results in Death**), Cardiac failure (102d - Fatal - **Results in Death**), Renal failure (102d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8241 | click or scan EU-EC-10010494990 | | 2021-10-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8242 | click or scan EU-EC-10010494980 | | 2021-10-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 8243 | click or scan EU-EC-10010494979 | | 2021-10-30 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonitis (24d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 8244 | click or scan EU-EC-10010494947 | | 2021-10-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Glioblastoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 8245 | click or scan EU-EC-10010493785 | | 2021-10-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8246 | click or scan EU-EC-10010493784 | | 2021-10-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8247 | click or scan EU-EC-10010493095 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8248 | click or scan EU-EC-10010493094 | | 2021-10-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8249 | click or scan EU-EC-10010493011 | | 2021-10-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8250 | click or scan EU-EC-10010493000 | | 2021-10-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8251 | click or scan EU-EC-10010492653 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Life Threatening), Cardiac failure (n/a - Fatal - **Results in Death**), Haematuria (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Life Threatening), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8252 | click or scan EU-EC-10010492533 | | 2021-10-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Oxygen saturation decreased (n/a - Unknown - ), Peripheral circulatory failure (n/a - Unknown - ), Pyelonephritis acute (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8253 | click or scan EU-EC-10010492471 | | 2021-10-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (55d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8254 | click or scan EU-EC-10010492408 | | 2021-10-29 | Healthcare Professional | EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8255 | click or scan EU-EC-10010492220 | | 2021-10-29 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8256 | click or scan EU-EC-10010491944 | | 2021-10-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 8257 | click or scan EU-EC-10010491604 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Basal ganglia haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8258 | click or scan EU-EC-10010491548 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8259 | click or scan EU-EC-10010491546 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthma (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8260 | click or scan EU-EC-10010491545 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary tuberculosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8261 | click or scan EU-EC-10010491542 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8262** | click or scan EU-EC-10010491541 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8263** | click or scan EU-EC-10010491527 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Asthma (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8264** | click or scan EU-EC-10010491526 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Encephalopathy (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8265** | click or scan EU-EC-10010491524 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8266** | click or scan EU-EC-10010491440 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **8267** | click or scan EU-EC-10010491223 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **8268** | click or scan EU-EC-10010491088 | | 2021-10-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Swelling (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), [BIOFLAVONOIDS, DIOSMIN, BIOFLAVONOIDS, DIOSMIN, HESPERIDIN, MICRONISED PURIFIED FLAVONOIC FRACTION] (I - n/a - n/a - [n/a - n/a - n/a]), [RIVAROXABAN] (I - n/a - n/a - [n/a - n/a - n/a]) |
| **8269** | click or scan EU-EC-10010491043 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Embolism venous (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8270 | click or scan EU-EC-10010490430 |  | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8271 | click or scan EU-EC-10010490408 |  | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8272 | click or scan EU-EC-10010490214 |  | 2021-10-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8273 | click or scan EU-EC-10010490167 |  | 2021-10-29 | Healthcare Professional | EEA | 18-64 Years | Female | Leiomyosarcoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8274 | click or scan EU-EC-10010490045 |  | 2021-10-29 | Healthcare Professional | EEA | 18-64 Years | Male | Colectomy (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8275 | click or scan EU-EC-10010489992 |  | 2021-10-29 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (S - Atrial fibrillation - Not applicable - [n/a - 1{DF} - Oral]), METHOTREXATE [METHOTREXATE] (S - Psoriasis - Not applicable - [n/a - 12.5mg - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (S - Gastrooesophageal reflux disease - Not applicable - [n/a - 40mg - Oral]), [FERROUS FUMARATE] (S - Deficiency anaemia - Not applicable - [n/a - 2{DF} - Oral]), [FOLIC ACID] (S - Prophylaxis - Not applicable - [n/a - 10mg - Oral]), [FUROSEMIDE] (S - Cardiac failure - Not applicable - [n/a - 60mg - Oral]), [PARACETAMOL] (S - Pain - Not applicable - [n/a - 3g - Oral]) |
| 8276 | click or scan EU-EC-10010489893 |  | 2021-10-29 | Healthcare Professional | EEA | 65-85 Years | Male | Adult failure to thrive (n/a - Fatal - **Results in Death**), Melaena (1d - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 8277 | click or scan EU-EC-10010489800 |  | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8278 | click or scan EU-EC-10010489799 |  | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8279 | click or scan EU-EC-10010489630 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrioventricular block (n/a - Unknown - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8280 | click or scan EU-EC-10010489627 | | 2021-10-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ), Medication error (n/a - Unknown - ), Off label use (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 8281 | click or scan EU-EC-10010489425 | | 2021-10-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Injection site pain (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8282 | click or scan EU-EC-10010489417 | | 2021-10-29 | Healthcare Professional | Non EEA | Not Specified | Male | Amnesia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8283 | click or scan EU-EC-10010489217 | | 2021-10-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8284 | click or scan EU-EC-10010489191 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8285 | click or scan EU-EC-10010489164 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8286 | click or scan EU-EC-10010488464 | | 2021-10-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8287 | click or scan EU-EC-10010488012 | | 2021-10-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8288 | click or scan EU-EC-10010487982 | | 2021-10-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aneurysm ruptured (n/a - Unknown - Other Medically Important Condition), Cholelithiasis (n/a - Unknown - ), Dysphonia (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8289 | click or scan EU-EC-10010487969 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8290 | click or scan EU-EC-10010487946 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute hepatitis B (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancreatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8291 | click or scan EU-EC-10010487911 | | 2021-10-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8292 | click or scan EU-EC-10010487898 | | 2021-10-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8293 | click or scan EU-EC-10010487812 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8294 | click or scan EU-EC-10010487772 | | 2021-10-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Joint swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intravenous (not otherwise specified)]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 8295 | click or scan EU-EC-10010487705 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8296 | click or scan EU-EC-10010487060 | | 2021-10-29 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8297 | click or scan EU-EC-10010486993 | | 2021-10-29 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8298 | click or scan EU-EC-10010486882 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8299 | click or scan EU-EC-10010486629 | | 2021-10-29 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 8300 | click or scan EU-EC-10010486056 | | 2021-10-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Chills (21d - Fatal - **Results in Death**), Death (21d - Fatal - **Results in Death**), Fatigue (21d - Fatal - **Results in Death**), Malaise (21d - Fatal - **Results in Death**), Nausea (21d - Fatal - **Results in Death**), Pyrexia (21d - Fatal - **Results in Death**), Respiratory failure (21d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8301 | click or scan EU-EC-10010486045 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 8302 | click or scan EU-EC-10010485715 | | 2021-10-29 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 8303 | click or scan EU-EC-10010484485 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arteriosclerosis (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mitral valve incompetence (n/a - Fatal - **Results in Death**), Papillary muscle disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8304 | click or scan EU-EC-10010484440 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 8305 | click or scan EU-EC-10010484403 | | 2021-10-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 8306 | click or scan EU-EC-10010484395 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure abnormal (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8307 | click or scan EU-EC-10010484187 | | 2021-10-29 | Non Healthcare Professional | Non EEA | Not Specified | Female | Adverse event (n/a - Unknown - ), Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 8308 | click or scan EU-EC-10010484044 | | 2021-10-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Chest pain (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8309** | click or scan EU-EC-10010482800 | | 2021-10-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), IIIrd nerve paralysis (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Petechiae (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Platelet factor 4 (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE] (S - Thrombotic thrombocytopenic purpura - Unknown - [n/a - n/a - Intravenous (not otherwise specified)]) |
| **8310** | click or scan EU-EC-10010482563 | | 2021-10-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Malaise (n/a - Unknown - ), Neck pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Vision blurred (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **8311** | click or scan EU-EC-10010482237 | | 2021-10-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Thrombotic stroke (n/a - Fatal - **Results in Death**), Transient aphasia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **8312** | click or scan EU-EC-10010480576 | | 2021-10-28 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8313** | click or scan EU-EC-10010480144 | | 2021-10-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Blindness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8314** | click or scan EU-EC-10010480138 | | 2021-10-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Exercise tolerance decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8315** | click or scan EU-EC-10010480087 | | 2021-10-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8316** | click or scan EU-EC-10010479045 | | 2021-10-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Brain operation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8317** | click or scan EU-EC-10010478722 | | 2021-10-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8318** | click or scan EU-EC-10010478663 | | 2021-10-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aggression (n/a - Fatal - **Results in Death**), Agitation (n/a - Fatal - **Results in Death**), Anger (n/a - Fatal - **Results in Death**), Crying (n/a - Fatal - **Results in Death**), Depression suicidal (n/a - Fatal - **Results in Death**), Hanging (0d - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Nightmare (n/a - Fatal - **Results in Death**), Paranoia (n/a - Fatal - **Results in Death**), Personality change (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**), Staring (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8319 | click or scan EU-EC-10010478536 | | 2021-10-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (9d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8320 | click or scan EU-EC-10010477827 | | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8321 | click or scan EU-EC-10010477819 | | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8322 | click or scan EU-EC-10010477733 | | 2021-10-28 | Healthcare Professional | EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening), Choking sensation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Infection (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Not Recovered/Not Resolved - Life Threatening), Myocardial necrosis marker increased (n/a - Unknown - Life Threatening), Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening), Pain (n/a - Unknown - Life Threatening), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 8323 | click or scan EU-EC-10010476462 | | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [29d - 2 {DF} - Intramuscular]) |
| 8324 | click or scan EU-EC-10010476394 | | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (23d - Fatal - **Results in Death**), Vaccination failure (23d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]) |
| 8325 | click or scan EU-EC-10010476360 | | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8326 | click or scan EU-EC-10010475785 | | 2021-10-28 | Healthcare Professional | EEA | Not Specified | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8327 | click or scan EU-EC-10010475394 | | 2021-10-28 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Chronic kidney disease (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Decubitus ulcer (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Lower gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malnutrition (n/a - Unknown - Other Medically Important Condition), Peripheral ischaemia (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8328** | click or scan EU-EC-10010474827 |  | 2021-10-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral ventricular rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8329** | click or scan EU-EC-10010474693 |  | 2021-10-28 | Healthcare Professional | EEA | More than 85 Years | Male | Dialysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic failure (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **8330** | click or scan EU-EC-10010474494 |  | 2021-10-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Thoracic haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **8331** | click or scan EU-EC-10010474408 |  | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Female | Purpura (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8332** | click or scan EU-EC-10010473504 |  | 2021-10-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Erythema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - ), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Swelling (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **8333** | click or scan EU-EC-10010473502 |  | 2021-10-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram ST segment elevation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tenderness (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vital signs measurement (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **8334** | click or scan EU-EC-10010472818 |  | 2021-10-28 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **8335** | click or scan EU-EC-10010472167 |  | 2021-10-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8336** | click or scan EU-EC-10010471931 |  | 2021-10-28 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate decreased (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **8337** | click or scan EU-EC-10010471458 |  | 2021-10-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Unknown - ), Locked-in syndrome (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - ), Product use issue (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8338** | click or scan EU-EC-10010471216 |  | 2021-10-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8339** | click or scan EU-EC-10010471214 |  | 2021-10-28 | Healthcare Professional | EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8340** | click or scan EU-EC-10010471213 |  | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8341** | click or scan EU-EC-10010471135 |  | 2021-10-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agonal respiration (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **8342** | click or scan EU-EC-10010471070 |  | 2021-10-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8343** | click or scan EU-EC-10010470692 |  | 2021-10-28 | Healthcare Professional | EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cytomegalovirus infection (n/a - Unknown - Other Medically Important Condition), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]), TACROLIMUS [TACROLIMUS, TACROLIMUS MONOHYDRATE] (S - Product used for unknown indication - Drug withdrawn - [172d - n/a - Unknown]) |
| **8344** | click or scan EU-EC-10010470451 |  | 2021-10-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8345** | click or scan EU-EC-10010470424 |  | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myeloid leukaemia (79d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Face oedema (79d - Fatal - **Results in Death**), Neutropenia (79d - Fatal - **Results in Death**), Pulmonary embolism (79d - Fatal - **Results in Death**), Thrombophlebitis (79d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8346** | click or scan EU-EC-10010470358 | | 2021-10-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **8347** | click or scan EU-EC-10010470206 | | 2021-10-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - ), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8348** | click or scan EU-EC-10010469863 | | 2021-10-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Herpes zoster (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Unknown - Caused/Prolonged Hospitalisation), Neuralgic amyotrophy (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Psychomotor retardation (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site movement impairment (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **8349** | click or scan EU-EC-10010469854 | | 2021-10-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **8350** | click or scan EU-EC-10010469812 | | 2021-10-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **8351** | click or scan EU-EC-10010469802 | | 2021-10-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8352 | click or scan EU-EC-10010469723 | | 2021-10-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchial wall thickening (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Erythema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding tube user (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mitral valve incompetence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mitral valve prolapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin lesion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin warm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin weeping (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Slow response to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8353 | click or scan EU-EC-10010469030 | | 2021-10-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8354 | click or scan EU-EC-10010467998 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Autopsy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Laboratory test (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8355 | click or scan EU-EC-10010467994 | | 2021-10-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (0d - Fatal - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pelvic pain (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8356 | click or scan EU-EC-10010467982 | | 2021-10-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8357 | click or scan EU-EC-10010467974 | | 2021-10-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - **Results in Death**), Influenza like illness (3d - Recovered/Resolved - **Results in Death**), Viral myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **8358** | click or scan EU-EC-10010467973 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal replacement therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vena cava thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8359** | click or scan EU-EC-10010467970 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **8360** | click or scan EU-EC-10010467643 | | 2021-10-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8361** | click or scan EU-EC-10010467559 | | 2021-10-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **8362** | click or scan EU-EC-10010467007 | | 2021-10-27 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Disabling), Foetal hypokinesia (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly), Umbilical cord abnormality (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **8363** | click or scan EU-EC-10010466727 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Monoparesis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **8364** | click or scan EU-EC-10010466552 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **8365** | click or scan EU-EC-10010466382 | | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8366** | click or scan EU-EC-10010466259 | | 2021-10-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Embolism (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8367 | click or scan EU-EC-10010466258 | | 2021-10-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancreatitis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8368 | click or scan EU-EC-10010465807 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive crisis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphadenopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Medication error (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Restlessness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8369 | click or scan EU-EC-10010465491 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Axillary vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiovascular disorder (n/a - Unknown - ), Erythema (n/a - Unknown - ), Lymphoedema (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Subclavian vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8370 | click or scan EU-EC-10010465411 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8371 | click or scan EU-EC-10010465321 | | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Female | Hallucination (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8372 | click or scan EU-EC-10010465307 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8373 | click or scan EU-EC-10010465287 | | 2021-10-27 | Healthcare Professional | EEA | Not Specified | Male | Limb malformation (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Limb reduction defect (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 8374 | click or scan EU-EC-10010465074 | | 2021-10-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8375 | click or scan EU-EC-10010464949 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 sepsis (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8376 | click or scan EU-EC-10010464850 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8377 | click or scan EU-EC-10010464754 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8378 | click or scan EU-EC-10010464747 | | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Respiratory acidosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8379 | click or scan EU-EC-10010464678 | | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8380 | click or scan EU-EC-10010464569 | | 2021-10-27 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8381 | click or scan EU-EC-10010464525 | | 2021-10-27 | Healthcare Professional | Non EEA | Not Specified | Male | Atrioventricular block (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8382 | click or scan EU-EC-10010464357 | | 2021-10-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coagulation time prolonged (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Infection (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Not Recovered/Not Resolved - Life Threatening), Nausea (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Renal impairment (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 8383 | click or scan EU-EC-10010464167 | | 2021-10-27 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8384 | click or scan EU-EC-10010464165 | | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8385 | click or scan EU-EC-10010464153 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **8386** | click or scan EU-EC-10010464038 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal perforation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8387** | click or scan EU-EC-10010463982 |  | 2021-10-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8388** | click or scan EU-EC-10010463966 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8389** | click or scan EU-EC-10010463875 |  | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Amylase increased (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8390** | click or scan EU-EC-10010463850 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8391** | click or scan EU-EC-10010463829 |  | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8392** | click or scan EU-EC-10010463827 |  | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cold sweat (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **8393** | click or scan EU-EC-10010463815 |  | 2021-10-27 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal malformation (n/a - Unknown - Other Medically Important Condition), Heart disease congenital (n/a - Unknown - Other Medically Important Condition), Umbilical cord around neck (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **8394** | click or scan EU-EC-10010463813 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8395 | click or scan EU-EC-10010463143 |  | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 8396 | click or scan EU-EC-10010463087 |  | 2021-10-27 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8397 | click or scan EU-EC-10010463086 |  | 2021-10-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8398 | click or scan EU-EC-10010463045 |  | 2021-10-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8399 | click or scan EU-EC-10010463010 |  | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Angina pectoris - n/a - [n/a - 100mg - Oral]), [BISOPROLOL HEMIFUMARATE] (S - Angina pectoris - n/a - [n/a - 1 {DF} - Oral]), [LACTULOSE, LACTULOSE, LIQUID] (S - n/a - n/a - [n/a - n/a - Oral]) |
| 8400 | click or scan EU-EC-10010462782 |  | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8401 | click or scan EU-EC-10010462705 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic infarction (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Transverse sinus thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8402 | click or scan EU-EC-10010462476 |  | 2021-10-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8403 | click or scan EU-EC-10010462473 |  | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8404 | click or scan EU-EC-10010462472 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8405 | click or scan EU-EC-10010462436 | | 2021-10-27 | Healthcare Professional | EEA | 18-64 Years | Male | Anxiety (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Pericarditis (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8406 | click or scan EU-EC-10010462408 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8407 | click or scan EU-EC-10010462392 | | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Hypoxia (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| 8408 | click or scan EU-EC-10010462256 | | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dysphagia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Immobile (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 8409 | click or scan EU-EC-10010462235 | | 2021-10-27 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8410 | click or scan EU-EC-10010462074 | | 2021-10-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 8411 | click or scan EU-EC-10010461969 | | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (8 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (8 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8412 | click or scan EU-EC-10010461924 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (21 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8413 | click or scan EU-EC-10010461913 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pupillary reflex impaired (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8414 | click or scan EU-EC-10010461797 | | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8415 | click or scan EU-EC-10010461732 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8416 | click or scan EU-EC-10010461504 | | 2021-10-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Guillain-Barre syndrome (70d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urosepsis (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8417 | click or scan EU-EC-10010461398 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Extra dose administered (1d - Recovered/Resolved - ), Multiple organ dysfunction syndrome (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8418 | click or scan EU-EC-10010461214 | | 2021-10-27 | Non Healthcare Professional | EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8419 | click or scan EU-EC-10010461186 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8420 | click or scan EU-EC-10010461004 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8421 | click or scan EU-EC-10010460889 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**), Dyspnoea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (11d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8422 | click or scan EU-EC-10010460859 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8423 | click or scan EU-EC-10010460742 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8424** | click or scan EU-EC-10010460657 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8425** | click or scan EU-EC-10010460656 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8426** | click or scan EU-EC-10010460463 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasal congestion (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8427** | click or scan EU-EC-10010460313 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8428** | click or scan EU-EC-10010460299 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8429** | click or scan EU-EC-10010459936 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8430** | click or scan EU-EC-10010459900 | | 2021-10-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - n/a]) |
| **8431** | click or scan EU-EC-10010459867 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **8432** | click or scan EU-EC-10010459708 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8433 | click or scan EU-EC-10010459668 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Transient ischaemic attack (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8434 | click or scan EU-EC-10010459593 |  | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Male | Ruptured cerebral aneurysm (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8435 | click or scan EU-EC-10010459394 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hereditary spherocytosis (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pulmonary hypertension (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8436 | click or scan EU-EC-10010459378 |  | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Staphylococcal sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8437 | click or scan EU-EC-10010459355 |  | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hyponatraemia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8438 | click or scan EU-EC-10010459269 |  | 2021-10-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8439 | click or scan EU-EC-10010459135 |  | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subdural haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8440 | click or scan EU-EC-10010458859 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8441 | click or scan EU-EC-10010458664 |  | 2021-10-27 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8442 | click or scan EU-EC-10010458617 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8443 | click or scan EU-EC-10010458571 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**), Fall (7d - Fatal - **Results in Death**), Fracture (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8444 | click or scan EU-EC-10010458555 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (6530min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (6530min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetes mellitus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (6530min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superinfection (6530min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8445 | click or scan EU-EC-10010458548 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (49d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8446 | click or scan EU-EC-10010458534 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8447 | click or scan EU-EC-10010458374 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Not Recovered/Not Resolved - ), Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8448 | click or scan EU-EC-10010458254 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8449 | click or scan EU-EC-10010458237 |  | 2021-10-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Foetal distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Premature baby (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR]) |
| 8450 | click or scan EU-EC-10010458215 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8451 | click or scan EU-EC-10010458208 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Unknown - ), Cerebrovascular disorder (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Recovered/Resolved - ), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8452 | click or scan EU-EC-10010458198 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8453 | click or scan EU-EC-10010458147 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8454 | click or scan EU-EC-10010458111 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immunisation (n/a - Unknown - ), Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8455 | click or scan EU-EC-10010457984 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8456 | click or scan EU-EC-10010457974 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal perforation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metastatic squamous cell carcinoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neuroendocrine tumour (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8457 | click or scan EU-EC-10010457885 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8458 | click or scan EU-EC-10010457869 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8459 | click or scan EU-EC-10010457861 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8460 | click or scan EU-EC-10010457812 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8461 | click or scan EU-EC-10010457762 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8462 | click or scan EU-EC-10010457707 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8463 | click or scan EU-EC-10010457675 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8464 | click or scan EU-EC-10010457648 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (1d - Fatal - **Results in Death**), Pulseless electrical activity (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8465 | click or scan EU-EC-10010457637 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8466 | click or scan EU-EC-10010457634 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8467 | click or scan EU-EC-10010457629 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8468 | click or scan EU-EC-10010457627 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stress cardiomyopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8469 | click or scan EU-EC-10010457608 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Communication disorder (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8470 | click or scan EU-EC-10010457520 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8471 | click or scan EU-EC-10010457303 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**), Cough (5d - Fatal - **Results in Death**), Pain (5d - Fatal - **Results in Death**), Respiratory tract congestion (5d - Fatal - **Results in Death**), Rhinorrhoea (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8472 | click or scan EU-EC-10010457275 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acquired diaphragmatic eventration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Adult failure to thrive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Lung infiltration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 8473 | click or scan EU-EC-10010456963 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (40d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8474 | click or scan EU-EC-10010456914 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8475 | click or scan EU-EC-10010456903 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**), Renal failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccine breakthrough infection (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8476 | click or scan EU-EC-10010456856 | | 2021-10-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8477 | click or scan EU-EC-10010456836 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8478 | click or scan EU-EC-10010456827 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Extensor plantar response (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Mydriasis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Photophobia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Slow speech (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - 1 {DF} - Intramuscular]) |
| 8479 | click or scan EU-EC-10010456728 | | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8480 | click or scan EU-EC-10010456594 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8481 | click or scan EU-EC-10010456552 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (1d - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Hypertensive heart disease (1d - Fatal - **Results in Death**), Pericardial haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8482 | click or scan EU-EC-10010456444 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8483 | click or scan EU-EC-10010456378 | | 2021-10-27 | Healthcare Professional | EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain herniation (1d - Fatal - **Results in Death**), Brain oedema (2d - Fatal - **Results in Death**), Cardiac arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cor pulmonale acute (2d - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8484 | click or scan EU-EC-10010456214 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8485 | click or scan EU-EC-10010456174 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8486 | click or scan EU-EC-10010456172 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), End stage renal disease (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8487 | click or scan EU-EC-10010456153 | | 2021-10-27 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8488 | click or scan EU-EC-10010456146 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8489 | click or scan EU-EC-10010456120 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8490 | click or scan EU-EC-10010456001 |  | 2021-10-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8491 | click or scan EU-EC-10010455995 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8492 | click or scan EU-EC-10010455945 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8493 | click or scan EU-EC-10010455938 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 8494 | click or scan EU-EC-10010455701 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8495 | click or scan EU-EC-10010455658 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | RIVAROXABAN [RIVAROXABAN] (I - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 8496 | click or scan EU-EC-10010455653 |  | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8497 | click or scan EU-EC-10010455638 |  | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8498** | click or scan EU-EC-10010455631 | | 2021-10-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Respiratory tract congestion (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8499** | click or scan EU-EC-10010455469 | | 2021-10-27 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8500** | click or scan EU-EC-10010455455 | | 2021-10-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaemia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), B-cell lymphoma (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Evans syndrome (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic lesion (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypokalaemia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Leukopenia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancytopenia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenomegaly (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8501** | click or scan EU-EC-10010455454 | | 2021-10-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8502** | click or scan EU-EC-10010455077 | | 2021-10-27 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (41d - Fatal - **Results in Death**), Asthenia (41d - Fatal - **Results in Death**), Blood creatine phosphokinase increased (41d - Fatal - **Results in Death**), Choluria (41d - Fatal - **Results in Death**), Decreased appetite (41d - Fatal - **Results in Death**), Hypokinesia (41d - Fatal - **Results in Death**), Malaise (41d - Fatal - **Results in Death**), Myalgia (41d - Fatal - **Results in Death**), Respiratory failure (41d - Fatal - **Results in Death**), Rhabdomyolysis (41d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Carotid artery occlusion - Drug withdrawn - [n/a - 80mg - Oral]) |
| **8503** | click or scan EU-EC-10010453608 | | 2021-10-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adult failure to thrive (19d - Fatal - **Results in Death**, Other Medically Important Condition), Asymptomatic COVID-19 (19d - Fatal - **Results in Death**), COVID-19 (19d - Fatal - **Results in Death**), Dementia (19d - Fatal - **Results in Death**, Other Medically Important Condition), Dementia Alzheimer's type (19d - Fatal - **Results in Death**, Other Medically Important Condition), Glaucoma (19d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperlipidaemia (19d - Fatal - **Results in Death**), Pulmonary hypertension (19d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (19d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8504** | click or scan EU-EC-10010453367 | | 2021-10-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumothorax (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure like phenomena (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular tachycardia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8505 | click or scan EU-EC-10010453182 |  | 2021-10-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Coagulopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Metabolic acidosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pyelonephritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal cortical necrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal ischaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8506 | click or scan EU-EC-10010453118 |  | 2021-10-26 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Respiratory distress (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8507 | click or scan EU-EC-10010452974 |  | 2021-10-26 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 8508 | click or scan EU-EC-10010451612 |  | 2021-10-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 8509 | click or scan EU-EC-10010451377 |  | 2021-10-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (4d - Recovered/Resolved - ), Hemiparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (4d - Recovered/Resolved - ), Pyrexia (4d - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 8510 | click or scan EU-EC-10010451303 |  | 2021-10-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Illness (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8511 | click or scan EU-EC-10010451276 |  | 2021-10-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8512 | click or scan EU-EC-10010451231 |  | 2021-10-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8513 | click or scan EU-EC-10010450918 |  | 2021-10-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8514 | click or scan EU-EC-10010450601 |  | 2021-10-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8515 | click or scan EU-EC-10010450445 | | 2021-10-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8516 | click or scan EU-EC-10010450271 | | 2021-10-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Acute respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8517 | click or scan EU-EC-10010449508 | | 2021-10-26 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [40d - 1 {DF} - Intramuscular]) |
| 8518 | click or scan EU-EC-10010449000 | | 2021-10-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Respiratory disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8519 | click or scan EU-EC-10010448942 | | 2021-10-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8520 | click or scan EU-EC-10010448862 | | 2021-10-26 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Adverse reaction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8521 | click or scan EU-EC-10010448128 | | 2021-10-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [TREPROSTINIL] (S - COVID-19 immunisation, Pulmonary arterial hypertension - Not applicable - [n/a - n/a - Respiratory (inhalation)]) |
| 8522 | click or scan EU-EC-10010446522 | | 2021-10-26 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8523 | click or scan EU-EC-10010446230 | | 2021-10-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyskinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile convulsion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tenderness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8524 | click or scan EU-EC-10010444280 | | 2021-10-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypercalcaemia (n/a - Recovering/Resolving - ), Hyperkalaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Interstitial lung disease (15d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Non-small cell lung cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal impairment (n/a - Recovering/Resolving - Other Medically Important Condition) | ALUNBRIG 90 MG [BRIGATINIB] (S - Non-small cell lung cancer - Unknown - [34d - 90mg - Oral - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 8525 | click or scan EU-EC-10010444280 | | 2021-10-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypercalcaemia (n/a - Recovering/Resolving - ), Hyperkalaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Interstitial lung disease (15d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Non-small cell lung cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal impairment (n/a - Recovering/Resolving - Other Medically Important Condition) | ALUNBRIG 90 MG [BRIGATINIB] (S - Non-small cell lung cancer - Unknown - [34d - 90mg - Oral - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Unknown - [n/a - 1 {DF} - Unknown]) |
| 8526 | click or scan EU-EC-10010441950 | | 2021-10-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (1d - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8527 | click or scan EU-EC-10010441909 | | 2021-10-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Accident (0d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100ug - Intramuscular]) |
| 8528 | click or scan EU-EC-10010441516 | | 2021-10-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac dysfunction (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decubitus ulcer (n/a - Unknown - ), Dysgraphia (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Haemorrhagic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - ), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8529 | click or scan EU-EC-10010441316 | | 2021-10-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac perforation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8530 | click or scan EU-EC-10010436942 | | 2021-10-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cough (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**), Respiratory failure (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8531 | click or scan EU-EC-10010436940 | | 2021-10-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cough (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**), Respiratory failure (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8532 | click or scan EU-EC-10010436554 | | 2021-10-26 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |
| 8533 | click or scan EU-EC-10010433986 | | 2021-10-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Eye injury (n/a - Fatal - **Results in Death**), Ischaemia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 8534 | click or scan EU-EC-10010431543 | | 2021-10-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Emphysema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fat embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Femur fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hip fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Therapy non-responder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ventilation/perfusion scan normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8535 | click or scan EU-EC-10010430718 | | 2021-10-25 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8536 | click or scan EU-EC-10010427913 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8537 | click or scan EU-EC-10010425105 | | 2021-10-25 | Healthcare Professional | EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**), Vaccine associated enhanced disease (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8538 | click or scan EU-EC-10010424838 | | 2021-10-25 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Mental impairment (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8539 | click or scan EU-EC-10010422812 | | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8540 | click or scan EU-EC-10010422632 | | 2021-10-25 | Healthcare Professional | EEA | 18-64 Years | Male | Encephalitis (n/a - Fatal - **Results in Death**), Myelitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8541 | click or scan EU-EC-10010422606 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8542 | click or scan EU-EC-10010422136 | | 2021-10-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8543 | click or scan EU-EC-10010421495 | | 2021-10-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (28d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8544 | click or scan EU-EC-10010421144 | | 2021-10-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Head discomfort (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Tension headache (n/a - Unknown - Other Medically Important Condition), Tinnitus (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8545 | click or scan EU-EC-10010419682 | | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8546 | click or scan EU-EC-10010419637 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Male | Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8547 | click or scan EU-EC-10010419599 | | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8548 | click or scan EU-EC-10010419597 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | Interstitial lung disease (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 8549 | click or scan EU-EC-10010419560 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Male | Rectal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), METHOTREXATE [METHOTREXATE] (S - Spondylitis - Not applicable - [n/a - 5mg - Oral]), SIMPONI 100 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE [GOLIMUMAB] (S - Spondylitis - Not applicable - [n/a - 1{DF} - Subcutaneous]), [ENOXAPARIN, ENOXAPARIN SODIUM] (S - Thrombosis prophylaxis - Not applicable - [n/a - n/a - Subcutaneous]), [ETHAMBUTOL HYDROCHLORIDE] (S - Tuberculosis - Not applicable - [n/a - 500mg - Oral]), [ISONIAZID] (S - Tuberculosis - Not applicable - [n/a - 300mg - Oral]), [PYRAZINAMIDE] (S - Tuberculosis - Not applicable - [n/a - 2000mg - Oral]), [RIFAMPICIN] (S - Tuberculosis - Not applicable - [n/a - 600mg - Oral]) |
| 8550 | click or scan EU-EC-10010419533 | | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Female | Agitation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 8551 | click or scan EU-EC-10010419522 | | 2021-10-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8552 | click or scan EU-EC-10010419279 | | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8553 | click or scan EU-EC-10010419277 | | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8554 | click or scan EU-EC-10010418984 |  | 2021-10-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal hernia (n/a - Unknown - ), Activated partial thromboplastin time shortened (n/a - Unknown - ), Anuria (n/a - Unknown - Other Medically Important Condition), Aortic arteriosclerosis (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Blood creatinine increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood immunoglobulin G increased (n/a - Unknown - ), Blood pressure fluctuation (n/a - Unknown - ), Blood sodium decreased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiac disorder (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Unknown - ), Eosinophil count increased (n/a - Unknown - ), Exercise tolerance decreased (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Full blood count abnormal (n/a - Unknown - ), Fungal test positive (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Glomerular filtration rate decreased (n/a - Unknown - ), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Hypertension (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Inflammation (n/a - Unknown - ), Interstitial lung disease (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Joint injury (n/a - Unknown - Other Medically Important Condition), Joint stiffness (n/a - Recovering/Resolving - Other Medically Important Condition), Joint swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Leukocytosis (n/a - Unknown - ), Loss of personal independence in daily activities (n/a - Unknown - ), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphopenia (n/a - Unknown - ), Malaise (n/a - Unknown - ), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Mean cell volume increased (n/a - Unknown - ), Metabolic acidosis (n/a - Unknown - ), Mitral valve incompetence (n/a - Unknown - Other Medically Important Condition), Monocyte count decreased (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Narcolepsy (n/a - Unknown - Other Medically Important Condition), Neutrophilia (n/a - Unknown - ), Normocytic anaemia (n/a - Unknown - ), Oedema peripheral (n/a - Recovered/Resolved - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), PCO2 decreased (n/a - Unknown - ), Pain (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Pneumocystis jirovecii infection (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition)... | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8555 | click or scan EU-EC-10010418740 |  | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dehydration (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (89d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 8556 | click or scan EU-EC-10010418228 |  | 2021-10-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**), Oedema (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8557 | click or scan EU-EC-10010417374 |  | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (5d - Fatal - **Results in Death**), Cardiac failure (5d - Fatal - **Results in Death**), Diarrhoea (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**), Vomiting (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 8558 | click or scan EU-EC-10010417356 |  | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (2d - Fatal - **Results in Death**), Cardiogenic shock (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 8559 | click or scan EU-EC-10010417137 |  | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Klebsiella infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superinfection bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8560 | click or scan EU-EC-10010416724 | | 2021-10-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8561 | click or scan EU-EC-10010416716 | | 2021-10-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8562 | click or scan EU-EC-10010414909 | | 2021-10-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abortion spontaneous (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8563 | click or scan EU-EC-10010414859 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8564 | click or scan EU-EC-10010414369 | | 2021-10-25 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8565 | click or scan EU-EC-10010413864 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 8566 | click or scan EU-EC-10010413860 | | 2021-10-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8567 | click or scan EU-EC-10010413825 | | 2021-10-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiopulmonary failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8568 | click or scan EU-EC-10010413030 | | 2021-10-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ejection fraction decreased (n/a - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypoxia (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Left ventricular dysfunction (n/a - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8569 | click or scan EU-EC-10010412994 | | 2021-10-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (2d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8570 | click or scan EU-EC-10010411513 | | 2021-10-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Drowning (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8571 | click or scan EU-EC-10010411366 | | 2021-10-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Bedridden (n/a - Unknown - ), Brain injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphemia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Intracranial pressure increased (n/a - Fatal - **Results in Death**), Migraine (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8572 | click or scan EU-EC-10010411183 | | 2021-10-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 8573 | click or scan EU-EC-10010410101 | | 2021-10-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8574 | click or scan EU-EC-10010408804 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemia (37d - Fatal - **Results in Death**), Renal failure (37d - Fatal - **Results in Death**), Respiratory failure (37d - Fatal - **Results in Death**), Vasculitis (37d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 8575 | click or scan EU-EC-10010408802 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (48d - Fatal - **Results in Death**), Respiratory failure (48d - Fatal - **Results in Death**), Vasculitis (48d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8576 | click or scan EU-EC-10010408785 | | 2021-10-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Lumbar vertebral fracture (51d - Fatal - **Results in Death**), Metastases to bone (51d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 8577 | click or scan EU-EC-10010408761 | | 2021-10-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Branchial cyst (17d - Fatal - **Results in Death**), Chest pain (17d - Fatal - **Results in Death**), Lymphadenopathy (17d - Fatal - **Results in Death**), Pericarditis (17d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8578 | click or scan EU-EC-10010408750 | | 2021-10-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8579 | click or scan EU-EC-10010408732 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Anaemia (14d - Fatal - **Results in Death**), Epistaxis (14d - Fatal - **Results in Death**), Thrombocytopenia (14d - Fatal - **Results in Death**), Thrombotic thrombocytopenic purpura (14d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 8580 | click or scan EU-EC-10010408719 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (8d - Fatal - **Results in Death**), Tachycardia (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8581 | click or scan EU-EC-10010408717 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Resuscitation (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8582 | click or scan EU-EC-10010408716 | | 2021-10-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 8583 | click or scan EU-EC-10010408715 | | 2021-10-23 | Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8584 | click or scan EU-EC-10010408714 | | 2021-10-23 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 8585 | click or scan EU-EC-10010408713 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary oedema (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mg - n/a]) |
| 8586 | click or scan EU-EC-10010408712 | | 2021-10-23 | Healthcare Professional | EEA | 65-85 Years | Female | Chest pain (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8587 | click or scan EU-EC-10010408709 | | 2021-10-23 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 300uL - Intramuscular]) |
| 8588 | click or scan EU-EC-10010408707 | | 2021-10-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Lymphadenopathy (88d - Fatal - **Results in Death**), Oropharyngeal pain (88d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8589 | click or scan EU-EC-10010408702 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 8590 | click or scan EU-EC-10010408700 | | 2021-10-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 8591 | click or scan EU-EC-10010408698 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - n/a]) |
| 8592 | click or scan EU-EC-10010408694 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Jugular vein thrombosis (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8593 | click or scan EU-EC-10010408692 | | 2021-10-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral artery thrombosis (4d - Fatal - **Results in Death**), Cerebrovascular accident (4d - Fatal - **Results in Death**), Ischaemic stroke (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8594 | click or scan EU-EC-10010408691 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 8595 | click or scan EU-EC-10010408689 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Female | Disseminated intravascular coagulation (5d - Fatal - **Results in Death**), Mesenteric vein thrombosis (5d - Fatal - **Results in Death**), Portal vein thrombosis (5d - Fatal - **Results in Death**), Splenic vein thrombosis (5d - Fatal - **Results in Death**), Thrombocytopenia (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 8596 | click or scan EU-EC-10010408687 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Female | Brain oedema (12d - Fatal - **Results in Death**), Cerebral haemorrhage (12d - Fatal - **Results in Death**), Cerebral thrombosis (12d - Fatal - **Results in Death**), Thrombocytopenia (12d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 8597 | click or scan EU-EC-10010408685 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 8598 | click or scan EU-EC-10010408683 | | 2021-10-23 | Healthcare Professional | EEA | 18-64 Years | Male | Hyperpyrexia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Rales (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8599 | click or scan EU-EC-10010407624 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dependence on oxygen therapy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 8600 | click or scan EU-EC-10010407135 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Gastrointestinal necrosis (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8601 | click or scan EU-EC-10010407056 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8602 | click or scan EU-EC-10010407055 | | 2021-10-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Mobility decreased (n/a - Unknown - ), Speech disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8603 | click or scan EU-EC-10010407033 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (3d - Fatal - **Results in Death**), Oxygen saturation decreased (3d - Fatal - **Results in Death**), Tachycardia (3d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8604 | click or scan EU-EC-10010407030 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8605 | click or scan EU-EC-10010406980 | | 2021-10-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8606 | click or scan EU-EC-10010406965 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8607 | click or scan EU-EC-10010406963 | | 2021-10-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (10d - Fatal - **Results in Death**), Dysphonia (10d - Fatal - **Results in Death**), Influenza like illness (10d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8608 | click or scan EU-EC-10010406962 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8609 | click or scan EU-EC-10010406960 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8610 | click or scan EU-EC-10010406884 | | 2021-10-22 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8611 | click or scan EU-EC-10010406541 | | 2021-10-22 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 8612 | click or scan EU-EC-10010406224 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8613 | click or scan EU-EC-10010406052 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (20d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (20d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8614 | click or scan EU-EC-10010405101 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8615 | click or scan EU-EC-10010404905 | | 2021-10-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8616 | click or scan EU-EC-10010404903 | | 2021-10-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8617 | click or scan EU-EC-10010404828 |  | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Ascites (n/a - Unknown - Other Medically Important Condition), Blood albumin increased (n/a - Unknown - Other Medically Important Condition), Blood cholinesterase increased (n/a - Unknown - Other Medically Important Condition), Blood lactate dehydrogenase increased (n/a - Unknown - Other Medically Important Condition), Blood pressure immeasurable (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Unknown - Other Medically Important Condition), Bradycardia (n/a - Unknown - Life Threatening), Cardiac arrest (n/a - Unknown - Life Threatening), Condition aggravated (n/a - Unknown - ), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic neoplasm (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Localised oedema (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pancreatic neoplasm (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Life Threatening), Ventricular tachycardia (n/a - Unknown - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8618 | click or scan EU-EC-10010404781 |  | 2021-10-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8619 | click or scan EU-EC-10010404398 |  | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain neoplasm (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Burns first degree (n/a - Unknown - Caused/Prolonged Hospitalisation), Burns second degree (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Enterobacter infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaginal infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8620 | click or scan EU-EC-10010404244 |  | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8621 | click or scan EU-EC-10010403219 |  | 2021-10-22 | Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bedridden (n/a - Unknown - ), Blindness cortical (n/a - Unknown - Other Medically Important Condition), Decubitus ulcer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Demyelination (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeding disorder (n/a - Unknown - ), Hepatic cyst (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune reconstitution inflammatory syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - ), Pneumonia (274d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Progressive multifocal leukoencephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Quadriplegia (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), TYSABRI [NATALIZUMAB] (S - Relapsing-remitting multiple sclerosis - Drug withdrawn - [2644d - 300mg - Unknown - More in ICSR]) |
| 8622 | click or scan EU-EC-10010403217 |  | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8623 | click or scan EU-EC-10010403161 |  | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8624 | click or scan EU-EC-10010403093 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) |
| 8625 | click or scan EU-EC-10010403070 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 8626 | click or scan EU-EC-10010403043 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 8627 | click or scan EU-EC-10010403012 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 8628 | click or scan EU-EC-10010403007 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8629 | click or scan EU-EC-10010402999 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular]) |
| 8630 | click or scan EU-EC-10010402990 | | 2021-10-22 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [71d - 3{DF} - Intramuscular]) |
| 8631 | click or scan EU-EC-10010402989 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| 8632 | click or scan EU-EC-10010402984 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [83d - 2{DF} - Intramuscular]) |
| 8633 | click or scan EU-EC-10010402979 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | Blood pressure decreased (15min - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8634 | click or scan EU-EC-10010402971 | | 2021-10-22 | Non Healthcare Professional | EEA | Not Specified | Female | Abortion induced (n/a - Fatal - **Results in Death**, Congenital Anomaly), Cerebral ventricle dilatation (n/a - Fatal - **Results in Death**, Congenital Anomaly), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - Foetal exposure during pregnancy - Not applicable - [1d - 1 {DF} - Transplacental]) |
| 8635 | click or scan EU-EC-10010402923 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Constipation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**), Gastric cancer recurrent (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8636 | click or scan EU-EC-10010402909 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Purpura (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin erosion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8637 | click or scan EU-EC-10010402884 | | 2021-10-22 | Healthcare Professional | Non EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8638 | click or scan EU-EC-10010402824 | | 2021-10-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), HIV infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal perforation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8639 | click or scan EU-EC-10010402473 | | 2021-10-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening), Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Life Threatening), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dialysis (n/a - Fatal - **Results in Death**, Life Threatening), Echocardiogram abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening), Fungal test (n/a - Fatal - **Results in Death**, Life Threatening), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening), Haemofiltration (n/a - Fatal - **Results in Death**, Life Threatening), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening), Mechanical ventilation (n/a - Fatal - **Results in Death**, Life Threatening), Pulse absent (n/a - Fatal - **Results in Death**, Life Threatening), Right ventricular dilatation (n/a - Fatal - **Results in Death**, Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Ultrasound Doppler normal (n/a - Fatal - **Results in Death**, Life Threatening), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening), Vascular catheterisation (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8640 | click or scan EU-EC-10010402468 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8641 | click or scan EU-EC-10010402430 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8642 | click or scan EU-EC-10010402224 |  | 2021-10-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (1d - Recovered/Resolved - ), Pain in extremity (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8643 | click or scan EU-EC-10010402091 |  | 2021-10-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8644 | click or scan EU-EC-10010401851 |  | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Platelet count decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8645 | click or scan EU-EC-10010401648 |  | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bacteraemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8646 | click or scan EU-EC-10010401622 |  | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8647 | click or scan EU-EC-10010401598 |  | 2021-10-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8648 | click or scan EU-EC-10010401597 |  | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8649 | click or scan EU-EC-10010401591 |  | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic stenosis (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8650 | click or scan EU-EC-10010401568 |  | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8651 | click or scan EU-EC-10010401566 |  | 2021-10-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8652 | click or scan EU-EC-10010401565 | | 2021-10-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Influenza like illness (n/a - Recovering/Resolving - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8653 | click or scan EU-EC-10010401530 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Immature granulocyte count increased (n/a - Unknown - ), Neutrophil count increased (n/a - Unknown - ), Pemphigoid (n/a - Recovered/Resolved - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8654 | click or scan EU-EC-10010401525 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stertor (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8655 | click or scan EU-EC-10010401439 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Female | Autoimmune haemolytic anaemia (155d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic lymphocytic leukaemia (155d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic cirrhosis (155d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8656 | click or scan EU-EC-10010401398 | | 2021-10-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 8657 | click or scan EU-EC-10010401313 | | 2021-10-22 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8658 | click or scan EU-EC-10010400772 | | 2021-10-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Administration site bruise (n/a - Unknown - ), Condition aggravated (n/a - Fatal - **Results in Death**), Hepatic fibrosis marker increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8659 | click or scan EU-EC-10010400356 | | 2021-10-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Illness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8660 | click or scan EU-EC-10010400264 | | 2021-10-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (2d - Fatal - **Results in Death**), Cardioversion (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (2d - Fatal - **Results in Death**), Respiratory arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8661 | click or scan EU-EC-10010400167 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bundle branch block left (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8662 | click or scan EU-EC-10010399122 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8663 | click or scan EU-EC-10010398938 | | 2021-10-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8664 | click or scan EU-EC-10010398925 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8665 | click or scan EU-EC-10010398860 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8666 | click or scan EU-EC-10010398752 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Embolism (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 8667 | click or scan EU-EC-10010398237 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8668 | click or scan EU-EC-10010398236 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8669 | click or scan EU-EC-10010398234 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8670 | click or scan EU-EC-10010398233 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8671 | click or scan EU-EC-10010398141 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8672 | click or scan EU-EC-10010398122 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - n/a]) |
| 8673 | click or scan EU-EC-10010397998 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8674 | click or scan EU-EC-10010397996 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8675 | click or scan EU-EC-10010397995 | | 2021-10-22 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8676 | click or scan EU-EC-10010397814 | | 2021-10-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8677 | click or scan EU-EC-10010397812 | | 2021-10-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8678 | click or scan EU-EC-10010397539 | | 2021-10-22 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation, Immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8679 | click or scan EU-EC-10010397416 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (1d - Unknown - Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (1d - Unknown - Other Medically Important Condition), Dyspnoea (1d - Unknown - Other Medically Important Condition), Syncope (1d - Unknown - Other Medically Important Condition), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition), Ventricular fibrillation (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8680 | click or scan EU-EC-10010397138 | | 2021-10-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Bradykinesia (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8681 | click or scan EU-EC-10010397113 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Aortic dissection rupture (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8682 | click or scan EU-EC-10010397083 | | 2021-10-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood lactate dehydrogenase increased (n/a - Unknown - ), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**), Liver disorder (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8683 | click or scan EU-EC-10010397034 | | 2021-10-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8684 | click or scan EU-EC-10010397025 | | 2021-10-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8685 | click or scan EU-EC-10010396769 | | 2021-10-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8686 | click or scan EU-EC-10010395600 | | 2021-10-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Gastrointestinal necrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Lower respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8687 | click or scan EU-EC-10010394079 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Injection site pain (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (79d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8688 | click or scan EU-EC-10010393364 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 8689 | click or scan EU-EC-10010393201 | | 2021-10-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8690 | click or scan EU-EC-10010392792 | | 2021-10-21 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 8691 | click or scan EU-EC-10010392743 | | 2021-10-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8692** | click or scan EU-EC-10010392692 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (13d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (13d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (13d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (13d - Unknown - Caused/Prolonged Hospitalisation), Chills (13d - Unknown - Caused/Prolonged Hospitalisation), Cough (13d - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (13d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (13d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (13d - Unknown - Caused/Prolonged Hospitalisation), Nausea (13d - Unknown - Caused/Prolonged Hospitalisation), Pain (13d - Unknown - Caused/Prolonged Hospitalisation), Pleuritic pain (13d - Unknown - Caused/Prolonged Hospitalisation), Vomiting (13d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8693** | click or scan EU-EC-10010392564 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Pulse abnormal (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8694** | click or scan EU-EC-10010392210 | | 2021-10-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Decreased appetite (n/a - Unknown - ), Hepatitis acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8695** | click or scan EU-EC-10010392178 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Cardiac discomfort (41d - Recovered/Resolved - ), Discomfort (4d - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (4d - Recovered/Resolved - ), Sleep disorder (4d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8696** | click or scan EU-EC-10010392164 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8697** | click or scan EU-EC-10010392112 | | 2021-10-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypothermia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **8698** | click or scan EU-EC-10010391160 | | 2021-10-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **8699** | click or scan EU-EC-10010391110 | | 2021-10-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8700** | click or scan EU-EC-10010391086 | | 2021-10-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| **8701** | click or scan EU-EC-10010391072 | | 2021-10-21 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8702** | click or scan EU-EC-10010389890 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Alanine aminotransferase decreased (n/a - Unknown - ), Albumin globulin ratio decreased (n/a - Unknown - ), Antinuclear antibody positive (n/a - Unknown - ), Blood albumin decreased (n/a - Unknown - ), Blood calcium decreased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood folate decreased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - ), Blood phosphorus increased (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - ), Blood pressure systolic decreased (n/a - Unknown - ), Blood sodium decreased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), Blood uric acid increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Eosinophil count decreased (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Immune thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Inflammation (n/a - Unknown - ), Lymphocyte count decreased (n/a - Unknown - ), Mean cell haemoglobin increased (n/a - Unknown - ), Nausea (n/a - Unknown - ), Neutrophil count increased (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Shunt stenosis (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thyroid function test abnormal (n/a - Unknown - ), Vitamin B12 abnormal (n/a - Unknown - ), Vomiting (n/a - Unknown - ), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8703** | click or scan EU-EC-10010389396 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Induration (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Toxic shock syndrome (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8704** | click or scan EU-EC-10010389325 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8705** | click or scan EU-EC-10010389173 | | 2021-10-21 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8706** | click or scan EU-EC-10010389165 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Recovered/Resolved - ), Dizziness (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8707** | click or scan EU-EC-10010389156 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1d - Fatal - **Results in Death**), Haematemesis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8708 | click or scan EU-EC-10010388849 | | 2021-10-21 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral artery occlusion (5d - Fatal - **Results in Death**), Cerebrovascular accident (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8709 | click or scan EU-EC-10010388734 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acidosis (n/a - Fatal - **Results in Death**), Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coagulopathy (n/a - Unknown - ), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Hyperkalaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8710 | click or scan EU-EC-10010388172 | | 2021-10-21 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8711 | click or scan EU-EC-10010388075 | | 2021-10-21 | Healthcare Professional | EEA | 65-85 Years | Male | Blood glucose increased (n/a - Fatal - **Results in Death**), Body temperature decreased (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 8712 | click or scan EU-EC-10010387980 | | 2021-10-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Unknown - ), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Metastasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 8713 | click or scan EU-EC-10010387728 | | 2021-10-21 | Healthcare Professional | EEA | 65-85 Years | Female | Clostridium test positive (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**), Staphylococcal bacteraemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 8714 | click or scan EU-EC-10010387668 | | 2021-10-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1min - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8715 | click or scan EU-EC-10010387399 | | 2021-10-21 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8716 | click or scan EU-EC-10010387397 | | 2021-10-21 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8717 | click or scan EU-EC-10010387386 | | 2021-10-21 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8718 | click or scan EU-EC-10010387246 | | 2021-10-21 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 8719 | click or scan EU-EC-10010387099 | | 2021-10-21 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8720 | click or scan EU-EC-10010386354 | | 2021-10-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (2d - Fatal - **Results in Death**), Coronary artery thrombosis (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8721 | click or scan EU-EC-10010386248 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8722 | click or scan EU-EC-10010385962 | | 2021-10-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8723 | click or scan EU-EC-10010385942 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dysstasia (n/a - Unknown - ), Fatigue (n/a - Recovered/Resolved - ), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8724 | click or scan EU-EC-10010385380 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8725 | click or scan EU-EC-10010385299 | | 2021-10-21 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 8726 | click or scan EU-EC-10010385020 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (2d - Fatal - **Results in Death**), Cough (3d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8727 | click or scan EU-EC-10010384893 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8728 | click or scan EU-EC-10010384475 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8729 | click or scan EU-EC-10010384283 | | 2021-10-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Choking sensation (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Urinary incontinence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8730 | click or scan EU-EC-10010384266 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (1d - Unknown - Other Medically Important Condition), Muscle twitching (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8731 | click or scan EU-EC-10010384170 | | 2021-10-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8732 | click or scan EU-EC-10010384110 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - ), Gastric haemorrhage (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8733 | click or scan EU-EC-10010383966 | | 2021-10-21 | Healthcare Professional | EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 8734 | click or scan EU-EC-10010383875 | | 2021-10-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8735 | click or scan EU-EC-10010383726 | | 2021-10-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8736 | click or scan EU-EC-10010383659 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8737 | click or scan EU-EC-10010383484 | | 2021-10-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8738 | click or scan EU-EC-10010382320 | | 2021-10-21 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (5d - Fatal - **Results in Death**, Life Threatening), Vaccination failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8739 | click or scan EU-EC-10010381384 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8740 | click or scan EU-EC-10010381303 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 8741 | click or scan EU-EC-10010381203 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8742 | click or scan EU-EC-10010381189 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Incorrect route of product administration (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Subcutaneous]), [CLOZAPINE] (S - Schizophrenia - Unknown - [n/a - 100mg - Oral]), [ZUCLOPENTHIXOL, ZUCLOPENTHIXOL ACETATE, ZUCLOPENTHIXOL DECANOATE, ZUCLOPENTHIXOL HYDROCHLORIDE] (S - Schizophrenia - Unknown - [n/a - 25mg - Oral - More in ICSR]) |
| 8743 | click or scan EU-EC-10010380550 | | 2021-10-20 | Healthcare Professional | Non EEA | Not Specified | Male | Deafness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8744 | click or scan EU-EC-10010379998 | | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood glucose decreased (90min - Recovered/Resolved - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8745 | click or scan EU-EC-10010379856 | | 2021-10-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8746 | click or scan EU-EC-10010379845 | | 2021-10-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (114d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Follicular lymphoma stage IV (98d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8747 | click or scan EU-EC-10010379587 | | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8748 | click or scan EU-EC-10010379582 | | 2021-10-20 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8749 | click or scan EU-EC-10010379581 | | 2021-10-20 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8750 | click or scan EU-EC-10010379580 | | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8751 | click or scan EU-EC-10010379263 | | 2021-10-20 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 8752 | click or scan EU-EC-10010379260 | | 2021-10-20 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8753 | click or scan EU-EC-10010379259 | | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8754 | click or scan EU-EC-10010379258 | | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8755 | click or scan EU-EC-10010379255 | | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 8756 | click or scan EU-EC-10010378541 | | 2021-10-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |
| 8757 | click or scan EU-EC-10010378537 | | 2021-10-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8758 | click or scan EU-EC-10010378534 |  | 2021-10-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} - Intramuscular]) |
| 8759 | click or scan EU-EC-10010378394 |  | 2021-10-20 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 8760 | click or scan EU-EC-10010378380 |  | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 8761 | click or scan EU-EC-10010378359 |  | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (17d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 8762 | click or scan EU-EC-10010378306 |  | 2021-10-20 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular - More in ICSR]) |
| 8763 | click or scan EU-EC-10010378204 |  | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 8764 | click or scan EU-EC-10010378103 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (186d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 8765 | click or scan EU-EC-10010377829 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (8d - Fatal - **Results in Death**), Hernia (8d - Fatal - **Results in Death**), Sudden death (8d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 8766 | click or scan EU-EC-10010377663 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8767 | click or scan EU-EC-10010377340 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Recovered/Resolved - ), Ageusia (n/a - Unknown - Caused/Prolonged Hospitalisation), Anosmia (n/a - Recovered/Resolved - ), Anosmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - ), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - ), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - ), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8768 | click or scan EU-EC-10010377013 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (8h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8769 | click or scan EU-EC-10010376980 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8770 | click or scan EU-EC-10010376947 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 8771 | click or scan EU-EC-10010376537 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (14d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (14d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (14d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (14d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea exertional (14d - Unknown - Caused/Prolonged Hospitalisation), Lung infiltration (14d - Unknown - Caused/Prolonged Hospitalisation), Oedema peripheral (14d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia bacterial (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (14d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8772 | click or scan EU-EC-10010376408 | | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 8773 | click or scan EU-EC-10010376323 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8774 | click or scan EU-EC-10010376289 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8775 | click or scan EU-EC-10010376200 | | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Malaise (12d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **8776** | click or scan EU-EC-10010376129 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Vaccine breakthrough infection (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8777** | click or scan EU-EC-10010376092 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cold sweat (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8778** | click or scan EU-EC-10010375709 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8779** | click or scan EU-EC-10010375651 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8780** | click or scan EU-EC-10010375474 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (29d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8781** | click or scan EU-EC-10010375172 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sick relative (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8782** | click or scan EU-EC-10010375084 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | General physical health deterioration (13d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (13d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (13d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8783** | click or scan EU-EC-10010375013 |  | 2021-10-20 | Healthcare Professional | EEA | More than 85 Years | Female | Coma (1d - Fatal - **Results in Death**), Epilepsy (n/a - Unknown - Other Medically Important Condition), Haemorrhagic cerebral infarction (1d - Fatal - **Results in Death**), Hypertensive crisis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **8784** | click or scan EU-EC-10010374702 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8785** | click or scan EU-EC-10010374361 |  | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 immunisation (n/a - Unknown - ), Electrolyte imbalance (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8786 | click or scan EU-EC-10010374348 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Flank pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8787 | click or scan EU-EC-10010373922 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (60d - Fatal - **Results in Death**, Other Medically Important Condition), Illness (60d - Fatal - **Results in Death**), Neoplasm malignant (60d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (60d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8788 | click or scan EU-EC-10010373255 |  | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8789 | click or scan EU-EC-10010373103 |  | 2021-10-20 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Guillain-Barre syndrome (6d - Fatal - **Results in Death**), Paraesthesia (n/a - Unknown - ), Paraesthesia oral (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8790 | click or scan EU-EC-10010372949 |  | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Cerebral disorder (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic function abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**), Mass (n/a - Unknown - Other Medically Important Condition), Mydriasis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pupillary reflex impaired (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**), Stress cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Ventricular hypokinesia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8791 | click or scan EU-EC-10010372931 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8792 | click or scan EU-EC-10010372837 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure chronic (2d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure congestive (2d - Fatal - **Results in Death**, Other Medically Important Condition), Chronic obstructive pulmonary disease (2d - Fatal - **Results in Death**), Condition aggravated (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8793 | click or scan EU-EC-10010372836 | | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Monoplegia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8794 | click or scan EU-EC-10010372587 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8795 | click or scan EU-EC-10010372179 | | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8796 | click or scan EU-EC-10010372102 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 8797 | click or scan EU-EC-10010371936 | | 2021-10-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug abuse (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 8798 | click or scan EU-EC-10010371902 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8799 | click or scan EU-EC-10010371901 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Carditis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8800 | click or scan EU-EC-10010371896 | | 2021-10-20 | Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8801 | click or scan EU-EC-10010371742 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8802 | click or scan EU-EC-10010371726 | | 2021-10-20 | Non Healthcare Professional | EEA | Not Specified | Female | Cardiac aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8803** | click or scan EU-EC-10010371667 |  | 2021-10-20 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8804** | click or scan EU-EC-10010371621 |  | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8805** | click or scan EU-EC-10010371515 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8806** | click or scan EU-EC-10010371512 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8807** | click or scan EU-EC-10010371361 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8808** | click or scan EU-EC-10010371313 |  | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aneurysm (38d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (38d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (69d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (38d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8809** | click or scan EU-EC-10010371108 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchiectasis (8d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (8d - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8810** | click or scan EU-EC-10010371099 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8811** | click or scan EU-EC-10010371084 |  | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **8812** | click or scan EU-EC-10010371018 |  | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Communication disorder (10d - Fatal - **Results in Death**), Immobile (10d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (10d - Fatal - **Results in Death**), Unresponsive to stimuli (10d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8813 | click or scan EU-EC-10010370995 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8814 | click or scan EU-EC-10010370842 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation), Face injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Lacunar infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8815 | click or scan EU-EC-10010370841 | | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8816 | click or scan EU-EC-10010370837 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac tamponade (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspepsia (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 8817 | click or scan EU-EC-10010370684 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrioventricular block complete (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac vein dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8818 | click or scan EU-EC-10010370656 | | 2021-10-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8819 | click or scan EU-EC-10010370617 | | 2021-10-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8820 | click or scan EU-EC-10010370506 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8821 | click or scan EU-EC-10010370405 | | 2021-10-20 | Healthcare Professional | EEA | 18-64 Years | Male | Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8822 | click or scan EU-EC-10010370299 | | 2021-10-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | B-cell lymphoma (n/a - Fatal - **Results in Death**), Haematopoietic neoplasm (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| 8823 | click or scan EU-EC-10010370138 | | 2021-10-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 8824 | click or scan EU-EC-10010369921 | | 2021-10-20 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Bradycardia foetal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 8825 | click or scan EU-EC-10010368717 | | 2021-10-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8826 | click or scan EU-EC-10010368304 | | 2021-10-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Balance disorder (n/a - Not Recovered/Not Resolved - ), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Gait disturbance (n/a - Not Recovered/Not Resolved - ), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8827 | click or scan EU-EC-10010368145 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular]) |
| 8828 | click or scan EU-EC-10010367966 | | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (n/a - Fatal - **Results in Death**), Chest X-ray normal (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8829 | click or scan EU-EC-10010367956 |  | 2021-10-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Escherichia infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatitis B (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8830 | click or scan EU-EC-10010367206 |  | 2021-10-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8831 | click or scan EU-EC-10010367127 |  | 2021-10-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Fatigue (15d - Fatal - **Results in Death**), Headache (15d - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral swelling (15d - Fatal - **Results in Death**), Skin discolouration (15d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8832 | click or scan EU-EC-10010366602 |  | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8833 | click or scan EU-EC-10010365678 |  | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Male | Bronchitis (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8834 | click or scan EU-EC-10010365014 |  | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiogenic shock (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8835 | click or scan EU-EC-10010364850 |  | 2021-10-19 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Gun shot wound (1d - Fatal - **Results in Death**), Haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8836 | click or scan EU-EC-10010364846 |  | 2021-10-19 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8837** | click or scan EU-EC-10010364840 | | 2021-10-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |
| **8838** | click or scan EU-EC-10010364823 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| **8839** | click or scan EU-EC-10010364820 | | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| **8840** | click or scan EU-EC-10010364819 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| **8841** | click or scan EU-EC-10010364818 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| **8842** | click or scan EU-EC-10010364817 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| **8843** | click or scan EU-EC-10010364814 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| **8844** | click or scan EU-EC-10010364812 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **8845** | click or scan EU-EC-10010364811 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| **8846** | click or scan EU-EC-10010364809 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8847 | click or scan EU-EC-10010364808 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Parenteral]) |
| 8848 | click or scan EU-EC-10010364785 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |
| 8849 | click or scan EU-EC-10010364747 | | 2021-10-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8850 | click or scan EU-EC-10010364744 | | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure congestive (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8851 | click or scan EU-EC-10010364741 | | 2021-10-19 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (9d - Fatal - **Results in Death**), Vaccination failure (9d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8852 | click or scan EU-EC-10010364740 | | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (14d - Fatal - **Results in Death**), Vaccination failure (14d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 8853 | click or scan EU-EC-10010364730 | | 2021-10-19 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8854 | click or scan EU-EC-10010364349 | | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Female | Joint swelling (n/a - Recovering/Resolving - ), Pancreatitis acute (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8855 | click or scan EU-EC-10010362708 | | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Aneurysm ruptured (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8856 | click or scan EU-EC-10010362506 | | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (2d - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (2d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8857 | click or scan EU-EC-10010362454 | | 2021-10-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inflammation (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8858 | click or scan EU-EC-10010362359 | | 2021-10-19 | Healthcare Professional | EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cytomegalovirus infection (n/a - Unknown - Other Medically Important Condition), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), TACROLIMUS [TACROLIMUS, TACROLIMUS MONOHYDRATE] (S - n/a - Drug withdrawn - [172d - n/a - Unknown]) |
| 8859 | click or scan EU-EC-10010362309 | | 2021-10-19 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8860 | click or scan EU-EC-10010362136 | | 2021-10-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [20d - 1 {DF} - Intramuscular]) |
| 8861 | click or scan EU-EC-10010361238 | | 2021-10-19 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 8862 | click or scan EU-EC-10010361237 | | 2021-10-19 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abortion missed (n/a - Fatal - **Results in Death**), Foetal death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 8863 | click or scan EU-EC-10010360989 | | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Male | Demyelinating polyneuropathy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 8864 | click or scan EU-EC-10010360603 | | 2021-10-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8865 | click or scan EU-EC-10010360461 | | 2021-10-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8866 | click or scan EU-EC-10010359823 | | 2021-10-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Infarction (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8867 | click or scan EU-EC-10010359358 |  | 2021-10-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 8868 | click or scan EU-EC-10010359326 |  | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Eye pain (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8869 | click or scan EU-EC-10010359322 |  | 2021-10-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8870 | click or scan EU-EC-10010359026 |  | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8871 | click or scan EU-EC-10010358974 |  | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Conjunctivitis (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Skin lesion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8872 | click or scan EU-EC-10010358945 |  | 2021-10-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8873 | click or scan EU-EC-10010358448 |  | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8874 | click or scan EU-EC-10010358445 |  | 2021-10-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8875 | click or scan EU-EC-10010358389 |  | 2021-10-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Exposure via breast milk (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary]) |
| 8876 | click or scan EU-EC-10010358378 |  | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8877 | click or scan EU-EC-10010358375 | | 2021-10-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8878 | click or scan EU-EC-10010358329 | | 2021-10-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening), Motor dysfunction (n/a - Fatal - **Results in Death**, Life Threatening), Thrombectomy (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8879 | click or scan EU-EC-10010358312 | | 2021-10-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Alanine aminotransferase increased (n/a - Unknown - ), Aspartate aminotransferase increased (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8880 | click or scan EU-EC-10010358290 | | 2021-10-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cellulitis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8881 | click or scan EU-EC-10010358266 | | 2021-10-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8882 | click or scan EU-EC-10010355932 | | 2021-10-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaphylactic shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac dysfunction (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8883 | click or scan EU-EC-10010355910 | | 2021-10-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - ), Urticaria (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8884 | click or scan EU-EC-10010355802 | | 2021-10-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a - More in ICSR]) |
| 8885 | click or scan EU-EC-10010355715 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Medication error (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Dose not changed - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8886 | click or scan EU-EC-10010355457 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (9d - Unknown - Caused/Prolonged Hospitalisation), Essential hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypovolaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal tubular necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep apnoea syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thirst (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 8887 | click or scan EU-EC-10010354950 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Dyspepsia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hypothermia (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial disease (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8888 | click or scan EU-EC-10010354336 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8889 | click or scan EU-EC-10010354133 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8890 | click or scan EU-EC-10010353687 | | 2021-10-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8891 | click or scan EU-EC-10010353618 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anal incontinence (n/a - Unknown - Other Medically Important Condition), Gastrointestinal disorder (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Skin abrasion (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8892 | click or scan EU-EC-10010352833 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle rigidity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (S - Nausea - Unknown - [n/a - n/a - Oral]) |
| 8893 | click or scan EU-EC-10010352458 | | 2021-10-18 | Healthcare Professional | EEA | 18-64 Years | Female | Pericardial effusion (n/a - Fatal - **Results in Death**), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8894 | click or scan EU-EC-10010352292 | | 2021-10-18 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 8895 | click or scan EU-EC-10010352268 | | 2021-10-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Concomitant disease aggravated (n/a - Unknown - Other Medically Important Condition), Respiratory acidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8896 | click or scan EU-EC-10010352074 | | 2021-10-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aspiration (n/a - Fatal - **Results in Death**), Choking (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8897 | click or scan EU-EC-10010352073 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8898 | click or scan EU-EC-10010352071 | | 2021-10-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 8899 | click or scan EU-EC-10010351928 | | 2021-10-18 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Purpura (27d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 8900 | click or scan EU-EC-10010351858 | | 2021-10-18 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Poor quality product administered (n/a - Fatal - **Results in Death**), Product temperature excursion issue (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8901 | click or scan EU-EC-10010351640 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Carotid arteriosclerosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspepsia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrointestinal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial fibrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neck pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 8902 | click or scan EU-EC-10010351541 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8903 | click or scan EU-EC-10010351199 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Communication disorder (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 8904 | click or scan EU-EC-10010351186 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8905 | click or scan EU-EC-10010351181 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8906 | click or scan EU-EC-10010350926 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8907 | click or scan EU-EC-10010350710 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8908 | click or scan EU-EC-10010350709 | | 2021-10-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (3d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8909 | click or scan EU-EC-10010350485 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arterial thrombosis (n/a - Fatal - **Results in Death**), Arteriosclerosis (n/a - Not Recovered/Not Resolved - Life Threatening), Dermatitis (n/a - Not Recovered/Not Resolved - Life Threatening), Dry gangrene (n/a - Not Recovered/Not Resolved - Life Threatening), Extremity necrosis (n/a - Not Recovered/Not Resolved - Life Threatening), Gangrene (n/a - Not Recovered/Not Resolved - Life Threatening), Haematological malignancy (n/a - Not Recovered/Not Resolved - Life Threatening), Iliac artery occlusion (n/a - Not Recovered/Not Resolved - Life Threatening), Mesenteric artery stenosis (n/a - Not Recovered/Not Resolved - Life Threatening), Penetrating aortic ulcer (n/a - Not Recovered/Not Resolved - Life Threatening), Peripheral arterial occlusive disease (n/a - Not Recovered/Not Resolved - Life Threatening), Psoriasis (n/a - Not Recovered/Not Resolved - Life Threatening), Renal infarct (n/a - Not Recovered/Not Resolved - Life Threatening), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening), Skin necrosis (n/a - Not Recovered/Not Resolved - Life Threatening), Skin ulcer (n/a - Not Recovered/Not Resolved - Life Threatening), Vasculitis (n/a - Not Recovered/Not Resolved - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 8910 | click or scan EU-EC-10010350483 | | 2021-10-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (16d - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8911 | click or scan EU-EC-10010350437 | | 2021-10-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8912** | click or scan EU-EC-10010350261 | | 2021-10-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8913** | click or scan EU-EC-10010350228 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8914** | click or scan EU-EC-10010350224 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic arteriosclerosis (n/a - Fatal - **Results in Death**), Aortic stenosis (n/a - Fatal - **Results in Death**), Aortic valve disease (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Mitral valve disease (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8915** | click or scan EU-EC-10010350195 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8916** | click or scan EU-EC-10010348880 | | 2021-10-18 | Healthcare Professional | EEA | 65-85 Years | Female | Embolism (114d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Infarction (114d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **8917** | click or scan EU-EC-10010347003 | | 2021-10-18 | Healthcare Professional | EEA | 65-85 Years | Female | Apathy (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| **8918** | click or scan EU-EC-10010346351 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Haematological malignancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **8919** | click or scan EU-EC-10010346222 | | 2021-10-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **8920** | click or scan EU-EC-10010345975 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8921** | click or scan EU-EC-10010345929 | | 2021-10-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8922** | click or scan EU-EC-10010345509 | | 2021-10-18 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8923** | click or scan EU-EC-10010345382 | | 2021-10-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Hypotonia (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8924** | click or scan EU-EC-10010345370 | | 2021-10-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8925** | click or scan EU-EC-10010345118 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Hypercapnia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8926** | click or scan EU-EC-10010345073 | | 2021-10-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), Electrocardiogram ST-T segment elevation (n/a - Unknown - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8927** | click or scan EU-EC-10010344971 | | 2021-10-18 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Cardiac failure (2wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8928** | click or scan EU-EC-10010344755 | | 2021-10-18 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **8929** | click or scan EU-EC-10010344689 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardiac failure chronic (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8930** | click or scan EU-EC-10010344684 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **8931** | click or scan EU-EC-10010344114 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | ADEMPAS [RIOCIGUAT] (S - Pulmonary arterial hypertension - Unknown - [n/a - n/a - n/a]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [TREPROSTINIL] (S - Pulmonary arterial hypertension - Unknown - [n/a - n/a - n/a]) |
| **8932** | click or scan EU-EC-10010344097 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8933 | click or scan EU-EC-10010344085 | | 2021-10-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8934 | click or scan EU-EC-10010344070 | | 2021-10-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 8935 | click or scan EU-EC-10010341168 | | 2021-10-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery disease (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 8936 | click or scan EU-EC-10010340275 | | 2021-10-16 | Healthcare Professional | EEA | 18-64 Years | Male | Hyperpyrexia (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8937 | click or scan EU-EC-10010339409 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8938 | click or scan EU-EC-10010339377 | | 2021-10-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 8939 | click or scan EU-EC-10010339291 | | 2021-10-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8940 | click or scan EU-EC-10010339288 | | 2021-10-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 8941 | click or scan EU-EC-10010339150 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 8942 | click or scan EU-EC-10010339145 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Penile swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8943** | click or scan EU-EC-10010339120 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Delirium (n/a - Unknown - Other Medically Important Condition), Hallucination (n/a - Unknown - Other Medically Important Condition), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Pneumonia staphylococcal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **8944** | click or scan EU-EC-10010339062 | | 2021-10-15 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial ischaemia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **8945** | click or scan EU-EC-10010338944 | | 2021-10-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **8946** | click or scan EU-EC-10010338774 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood cholesterol increased (n/a - Not Recovered/Not Resolved - ), Blood triglycerides increased (n/a - Not Recovered/Not Resolved - ), Chest discomfort (n/a - Not Recovered/Not Resolved - ), Condition aggravated (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Unknown - ), Tachycardia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8947** | click or scan EU-EC-10010338635 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (13d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypersensitivity (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Swelling face (0d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Swollen tongue (3d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8948** | click or scan EU-EC-10010338428 | | 2021-10-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8949** | click or scan EU-EC-10010338355 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diabetes mellitus (1d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **8950** | click or scan EU-EC-10010338142 | | 2021-10-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8951** | click or scan EU-EC-10010338088 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8952** | click or scan EU-EC-10010337859 | | 2021-10-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abnormal weight gain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved - ), Fall (0d - Unknown - ), Head injury (n/a - Unknown - ), Hospitalisation (n/a - Not Recovered/Not Resolved - ), Oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **8953** | click or scan EU-EC-10010337139 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8954** | click or scan EU-EC-10010336781 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **8955** | click or scan EU-EC-10010336780 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (8d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Headache (8d - Fatal - **Results in Death**), Leukaemia (2d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (6d - Fatal - **Results in Death**), Peripheral circulatory failure (2d - Fatal - **Results in Death**), Pyrexia (9d - Fatal - **Results in Death**), Vomiting (7d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **8956** | click or scan EU-EC-10010336771 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8957** | click or scan EU-EC-10010336031 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **8958** | click or scan EU-EC-10010335910 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **8959** | click or scan EU-EC-10010335881 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **8960** | click or scan EU-EC-10010335879 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **8961** | click or scan EU-EC-10010335860 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8962** | click or scan EU-EC-10010335858 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **8963** | click or scan EU-EC-10010335804 | | 2021-10-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8964** | click or scan EU-EC-10010335788 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **8965** | click or scan EU-EC-10010335670 | | 2021-10-15 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Painful respiration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **8966** | click or scan EU-EC-10010335539 | | 2021-10-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8967** | click or scan EU-EC-10010335514 | | 2021-10-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Myalgia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8968** | click or scan EU-EC-10010335509 | | 2021-10-15 | Non Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **8969** | click or scan EU-EC-10010334991 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Expired product administered (n/a - Unknown - ), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **8970** | click or scan EU-EC-10010334978 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8971** | click or scan EU-EC-10010334856 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **8972** | click or scan EU-EC-10010334807 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **8973** | click or scan EU-EC-10010334613 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **8974** | click or scan EU-EC-10010334493 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8975** | click or scan EU-EC-10010334491 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), New onset diabetes after transplantation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **8976** | click or scan EU-EC-10010334338 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8977** | click or scan EU-EC-10010334306 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **8978** | click or scan EU-EC-10010334278 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8979** | click or scan EU-EC-10010334228 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **8980** | click or scan EU-EC-10010334227 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **8981** | click or scan EU-EC-10010334080 | | 2021-10-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cardiovascular symptom (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **8982** | click or scan EU-EC-10010334031 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8983** | click or scan EU-EC-10010334027 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 8984 | click or scan EU-EC-10010334017 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 8985 | click or scan EU-EC-10010333936 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8986 | click or scan EU-EC-10010333935 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8987 | click or scan EU-EC-10010333934 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8988 | click or scan EU-EC-10010333933 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8989 | click or scan EU-EC-10010333919 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 8990 | click or scan EU-EC-10010333799 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Incontinence (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 8991 | click or scan EU-EC-10010333795 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8992 | click or scan EU-EC-10010333794 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8993 | click or scan EU-EC-10010333793 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 8994 | click or scan EU-EC-10010333792 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **8995** | click or scan EU-EC-10010333791 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **8996** | click or scan EU-EC-10010333790 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **8997** | click or scan EU-EC-10010333565 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **8998** | click or scan EU-EC-10010333451 | | 2021-10-15 | Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **8999** | click or scan EU-EC-10010332941 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9000** | click or scan EU-EC-10010332290 | | 2021-10-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Bradycardia (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyporesponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Presyncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9001** | click or scan EU-EC-10010332284 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Immunisation (n/a - Unknown - ), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9002** | click or scan EU-EC-10010332279 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Hepatic necrosis (n/a - Unknown - Other Medically Important Condition), Intestinal ischaemia (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pyelonephritis acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal graft infection (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic infection (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9003** | click or scan EU-EC-10010332264 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bronchitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9004** | click or scan EU-EC-10010332234 | | 2021-10-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9005** | click or scan EU-EC-10010332219 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Paraesthesia oral (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Vaccination site erythema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9006** | click or scan EU-EC-10010332212 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9007** | click or scan EU-EC-10010332146 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **9008** | click or scan EU-EC-10010332145 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **9009** | click or scan EU-EC-10010332144 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **9010** | click or scan EU-EC-10010332143 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **9011** | click or scan EU-EC-10010332142 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **9012** | click or scan EU-EC-10010332097 | | 2021-10-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthma (1d - Fatal - **Results in Death**), Overdose (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9013** | click or scan EU-EC-10010332008 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **9014** | click or scan EU-EC-10010332006 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9015** | click or scan EU-EC-10010331858 | | 2021-10-15 | Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9016** | click or scan EU-EC-10010331728 | | 2021-10-15 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **9017** | click or scan EU-EC-10010331621 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9018** | click or scan EU-EC-10010331595 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9019** | click or scan EU-EC-10010331561 | | 2021-10-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Coronary artery stenosis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9020** | click or scan EU-EC-10010331535 | | 2021-10-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acidosis (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haematoma (n/a - Recovered/Resolved - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9021** | click or scan EU-EC-10010331457 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Head injury (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9022** | click or scan EU-EC-10010331317 | | 2021-10-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| **9023** | click or scan EU-EC-10010331292 | | 2021-10-15 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Haemoglobin decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9024** | click or scan EU-EC-10010331274 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9025 | click or scan EU-EC-10010331271 | | 2021-10-15 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9026 | click or scan EU-EC-10010331258 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9027 | click or scan EU-EC-10010331042 | | 2021-10-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Apnoea (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (1d - Unknown - ), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Snoring (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9028 | click or scan EU-EC-10010330881 | | 2021-10-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9029 | click or scan EU-EC-10010330516 | | 2021-10-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mitral valve incompetence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9030 | click or scan EU-EC-10010330310 | | 2021-10-15 | Healthcare Professional | EEA | 18-64 Years | Female | Arterial occlusive disease (52d - Fatal - **Results in Death**), Capillary permeability increased (52d - Fatal - **Results in Death**), Retinal vascular thrombosis (52d - Fatal - **Results in Death**), Thrombotic microangiopathy (52d - Fatal - **Results in Death**), Transverse sinus thrombosis (52d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 9031 | click or scan EU-EC-10010330305 | | 2021-10-15 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 9032 | click or scan EU-EC-10010330295 | | 2021-10-15 | Healthcare Professional | EEA | More than 85 Years | Female | Decreased appetite (0d - Fatal - **Results in Death**), Diarrhoea (0d - Fatal - **Results in Death**), Hyperpyrexia (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9033 | click or scan EU-EC-10010329747 | | 2021-10-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Herpes zoster (n/a - Fatal - **Results in Death**), Pneumonia bacterial (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1 {DF} - Intramuscular]) |
| 9034 | click or scan EU-EC-10010328525 | | 2021-10-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9035 | click or scan EU-EC-10010328454 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9036 | click or scan EU-EC-10010328163 | | 2021-10-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - 1 {DF} - Intramuscular]) |
| 9037 | click or scan EU-EC-10010328160 | | 2021-10-14 | Healthcare Professional | Non EEA | Not Specified | Female | Brain injury (n/a - Not Recovered/Not Resolved - Life Threatening), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening), Dementia (n/a - Not Recovered/Not Resolved - Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Transient ischaemic attack (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9038 | click or scan EU-EC-10010327807 | | 2021-10-14 | Healthcare Professional | Non EEA | Not Specified | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]), XOFIGO [RADIUM RA 223 DICHLORIDE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 9039 | click or scan EU-EC-10010327651 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9040 | click or scan EU-EC-10010327649 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9041 | click or scan EU-EC-10010327555 | | 2021-10-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Tissue injury (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9042 | click or scan EU-EC-10010327472 | | 2021-10-14 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac asthma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9043 | click or scan EU-EC-10010327235 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ascites (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atelectasis (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral atrophy (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral small vessel ischaemic disease (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastric ulcer perforation (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung consolidation (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Weaning failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9044 | click or scan EU-EC-10010326837 | | 2021-10-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (24d - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), COVID-19 (24d - Unknown - Other Medically Important Condition), Chronic kidney disease (24d - Unknown - Other Medically Important Condition), Cough (24d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (24d - Unknown - Other Medically Important Condition), Dyspnoea (24d - Unknown - Other Medically Important Condition), Movement disorder (24d - Unknown - Other Medically Important Condition), Pyrexia (24d - Unknown - Other Medically Important Condition), Sepsis (24d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9045 | click or scan EU-EC-10010324634 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neoplasm malignant (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal tubular necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rib fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular fibrillation (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9046 | click or scan EU-EC-10010324629 | | 2021-10-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9047 | click or scan EU-EC-10010322656 | | 2021-10-14 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), SARS-CoV-2 test positive (6d - Not Recovered/Not Resolved - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9048 | click or scan EU-EC-10010322518 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (7d - Unknown - Other Medically Important Condition), Confusional state (7d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Memory impairment (7d - Unknown - Other Medically Important Condition), Posture abnormal (7d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9049 | click or scan EU-EC-10010322246 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bed rest (n/a - Recovering/Resolving - ), Chest pain (n/a - Recovering/Resolving - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - ), Inappropriate schedule of product administration (n/a - Unknown - ), Vaccination complication (n/a - Recovering/Resolving - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9050 | click or scan EU-EC-10010322230 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9051** | click or scan EU-EC-10010321979 |  | 2021-10-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **9052** | click or scan EU-EC-10010321973 |  | 2021-10-14 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| **9053** | click or scan EU-EC-10010321971 |  | 2021-10-14 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [26d - 1{DF} - Intramuscular]) |
| **9054** | click or scan EU-EC-10010321347 |  | 2021-10-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **9055** | click or scan EU-EC-10010321263 |  | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dizziness (n/a - Unknown - Life Threatening), Dysstasia (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **9056** | click or scan EU-EC-10010321231 |  | 2021-10-14 | Healthcare Professional | EEA | More than 85 Years | Male | Bronchitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **9057** | click or scan EU-EC-10010320991 |  | 2021-10-14 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **9058** | click or scan EU-EC-10010320839 |  | 2021-10-14 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **9059** | click or scan EU-EC-10010320801 |  | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Status epilepticus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9060** | click or scan EU-EC-10010320635 |  | 2021-10-14 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9061** | click or scan EU-EC-10010320585 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9062** | click or scan EU-EC-10010320510 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9063** | click or scan EU-EC-10010320453 | | 2021-10-14 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **9064** | click or scan EU-EC-10010320436 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (8d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (8d - Unknown - Caused/Prolonged Hospitalisation), Weight decreased (8d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9065** | click or scan EU-EC-10010320269 | | 2021-10-14 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **9066** | click or scan EU-EC-10010320255 | | 2021-10-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9067** | click or scan EU-EC-10010319885 | | 2021-10-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Blister (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Blood sodium decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Contusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Hypothyroidism (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Rash erythematous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Skin infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9068** | click or scan EU-EC-10010319821 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Discomfort (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial pressure increased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Ocular discomfort (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Venous haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9069** | click or scan EU-EC-10010318751 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9070 | click or scan EU-EC-10010318653 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9071 | click or scan EU-EC-10010318575 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9072 | click or scan EU-EC-10010318560 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9073 | click or scan EU-EC-10010318475 | | 2021-10-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9074 | click or scan EU-EC-10010318290 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | General physical health deterioration (19d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9075 | click or scan EU-EC-10010318278 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9076 | click or scan EU-EC-10010318265 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary vascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 9077 | click or scan EU-EC-10010318198 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9078 | click or scan EU-EC-10010318039 | | 2021-10-14 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9079** | click or scan EU-EC-10010317907 | | 2021-10-14 | Healthcare Professional | EEA | 18-64 Years | Male | Toxic skin eruption (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]), ZYDELIG [IDELALISIB] (S - Follicular lymphoma - Drug withdrawn - [n/a - 150mg - Oral]) |
| **9080** | click or scan EU-EC-10010317863 | | 2021-10-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9081** | click or scan EU-EC-10010317850 | | 2021-10-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9082** | click or scan EU-EC-10010317669 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9083** | click or scan EU-EC-10010317611 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (53d - Unknown - ), Abdominal distension (n/a - Unknown - ), Asthenia (53d - Unknown - ), Atelectasis (53d - Unknown - ), Back pain (53d - Unknown - ), Cardiac arrest (4d - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (53d - Fatal - **Results in Death**), Decreased appetite (53d - Unknown - ), Dizziness (53d - Unknown - ), Dizziness (n/a - Unknown - ), Dyspepsia (n/a - Unknown - ), Fatigue (53d - Unknown - ), Lung infiltration (53d - Unknown - ), Myocardial infarction (4d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (53d - Unknown - ), Unresponsive to stimuli (4d - Fatal - **Results in Death**, Other Medically Important Condition), Weight decreased (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **9084** | click or scan EU-EC-10010317564 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9085** | click or scan EU-EC-10010317279 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9086** | click or scan EU-EC-10010317006 | | 2021-10-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hypoxia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9087** | click or scan EU-EC-10010316938 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral amyloid angiopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9088** | click or scan EU-EC-10010316345 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphoma (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9089** | click or scan EU-EC-10010316280 |  | 2021-10-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9090** | click or scan EU-EC-10010316107 |  | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (43d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9091** | click or scan EU-EC-10010316071 |  | 2021-10-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (5d - Fatal - **Results in Death**), Coma (1d - Fatal - **Results in Death**), Malaise (5d - Fatal - **Results in Death**) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **9092** | click or scan EU-EC-10010315927 |  | 2021-10-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **9093** | click or scan EU-EC-10010315749 |  | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Condition aggravated (1d - Fatal - **Results in Death**), Confusional state (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (1d - Fatal - **Results in Death**), Septic shock (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9094** | click or scan EU-EC-10010315673 |  | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9095** | click or scan EU-EC-10010315648 |  | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Coronary artery thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Full blood count abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Interleukin level increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Joint swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nail bed bleeding (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - ), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Subacute endocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Vasculitic rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Vasculitis (n/a - Fatal - **Results in Death**), White blood cell count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9096** | click or scan EU-EC-10010315615 |  | 2021-10-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| **9097** | click or scan EU-EC-10010315375 |  | 2021-10-14 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9098 | click or scan EU-EC-10010315340 | | 2021-10-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9099 | click or scan EU-EC-10010315337 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9100 | click or scan EU-EC-10010315299 | | 2021-10-14 | Healthcare Professional | EEA | More than 85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 9101 | click or scan EU-EC-10010315282 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Extra dose administered (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9102 | click or scan EU-EC-10010315278 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9103 | click or scan EU-EC-10010315233 | | 2021-10-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 9104 | click or scan EU-EC-10010315204 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Decubitus ulcer (n/a - Fatal - **Results in Death**), Dialysis related complication (n/a - Fatal - **Results in Death**), End stage renal disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9105 | click or scan EU-EC-10010315136 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9106 | click or scan EU-EC-10010315125 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9107 | click or scan EU-EC-10010315124 | | 2021-10-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Musculoskeletal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9108 | click or scan EU-EC-10010315110 | | 2021-10-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9109 | click or scan EU-EC-10010315066 |  | 2021-10-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure increased (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9110 | click or scan EU-EC-10010315054 |  | 2021-10-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9111 | click or scan EU-EC-10010314576 |  | 2021-10-14 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 9112 | click or scan EU-EC-10010312986 |  | 2021-10-13 | Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9113 | click or scan EU-EC-10010312936 |  | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anion gap increased (n/a - Unknown - ), Blood bicarbonate decreased (n/a - Unknown - ), Blood chloride decreased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood fibrinogen increased (n/a - Unknown - ), Blood immunoglobulin E increased (n/a - Unknown - ), Blood potassium decreased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), Bone swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown - ), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Mean cell haemoglobin decreased (n/a - Unknown - ), Mean cell volume decreased (n/a - Unknown - ), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9114 | click or scan EU-EC-10010312832 |  | 2021-10-13 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9115 | click or scan EU-EC-10010312719 |  | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 9116 | click or scan EU-EC-10010312580 |  | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9117 | click or scan EU-EC-10010312492 |  | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9118 | click or scan EU-EC-10010312425 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9119 | click or scan EU-EC-10010312331 | | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9120 | click or scan EU-EC-10010312185 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9121 | click or scan EU-EC-10010311657 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9122 | click or scan EU-EC-10010311538 | | 2021-10-13 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 9123 | click or scan EU-EC-10010311351 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9124 | click or scan EU-EC-10010311189 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anal incontinence (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9125 | click or scan EU-EC-10010311068 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9126 | click or scan EU-EC-10010310942 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9127 | click or scan EU-EC-10010310835 | | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Eosinophilic myocarditis (n/a - Fatal - **Results in Death**), Myalgia (n/a - Recovered/Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9128 | click or scan EU-EC-10010310818 | | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (3d - Recovered/Resolved - ), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved - ), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9129 | click or scan EU-EC-10010310787 | | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Male | Alcohol use (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Coronary artery stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9130 | click or scan EU-EC-10010310786 | | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9131 | click or scan EU-EC-10010310541 | | 2021-10-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Hepatic infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatic infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Truncus coeliacus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9132 | click or scan EU-EC-10010310411 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (14d - Fatal - **Results in Death**), Cough (14d - Fatal - **Results in Death**), Dyspnoea (14d - Fatal - **Results in Death**), Fatigue (14d - Fatal - **Results in Death**), Pyrexia (14d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9133 | click or scan EU-EC-10010310222 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anuria (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumothorax (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Withdrawal of life support (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9134 | click or scan EU-EC-10010310207 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Interchange of vaccine products (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9135 | click or scan EU-EC-10010309939 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9136 | click or scan EU-EC-10010309865 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9137 | click or scan EU-EC-10010309810 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9138 | click or scan EU-EC-10010309762 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9139 | click or scan EU-EC-10010309738 | | 2021-10-13 | Healthcare Professional | EEA | More than 85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9140 | click or scan EU-EC-10010309676 | | 2021-10-13 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9141 | click or scan EU-EC-10010309253 | | 2021-10-13 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 9142 | click or scan EU-EC-10010309240 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9143 | click or scan EU-EC-10010309203 | | 2021-10-13 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9144 | click or scan EU-EC-10010309109 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9145 | click or scan EU-EC-10010308812 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Life Threatening, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9146 | click or scan EU-EC-10010308801 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocarditis (55d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9147 | click or scan EU-EC-10010308786 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9148 | click or scan EU-EC-10010308409 |  | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Lung opacity (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Plateletcrit increased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**), White blood cell count increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9149 | click or scan EU-EC-10010308400 |  | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Oxygen saturation decreased (n/a - Unknown - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9150 | click or scan EU-EC-10010308377 |  | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9151 | click or scan EU-EC-10010308325 |  | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - Subcutaneous]) |
| 9152 | click or scan EU-EC-10010308271 |  | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9153 | click or scan EU-EC-10010308179 |  | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9154 | click or scan EU-EC-10010308031 |  | 2021-10-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Foot fracture (n/a - Not Recovered/Not Resolved - ), Hemiparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Not Recovered/Not Resolved - Life Threatening), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9155 | click or scan EU-EC-10010307684 |  | 2021-10-13 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9156 | click or scan EU-EC-10010307362 |  | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9157** | click or scan EU-EC-10010307324 | | 2021-10-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dehydration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gastritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Immunisation reaction (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [FLUINDIONE] (S - Atrial fibrillation - Drug withdrawn - [n/a - n/a - Oral]) |
| **9158** | click or scan EU-EC-10010307038 | | 2021-10-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Hemiparaesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **9159** | click or scan EU-EC-10010306380 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Incorrect route of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous]) |
| **9160** | click or scan EU-EC-10010306208 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coma (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic stroke (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **9161** | click or scan EU-EC-10010306192 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **9162** | click or scan EU-EC-10010306085 | | 2021-10-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Feeding disorder (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9163** | click or scan EU-EC-10010306053 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **9164** | click or scan EU-EC-10010305972 | | 2021-10-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **9165** | click or scan EU-EC-10010305939 | | 2021-10-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Swelling (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Urinary retention (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9166** | click or scan EU-EC-10010305761 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9167 | click or scan EU-EC-10010305692 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 9168 | click or scan EU-EC-10010305606 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anxiety (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest discomfort (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic respiratory failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercapnia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep disorder (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 9169 | click or scan EU-EC-10010305521 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 9170 | click or scan EU-EC-10010305415 | | 2021-10-13 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9171 | click or scan EU-EC-10010305213 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Intentional removal of drug delivery system by patient (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 9172 | click or scan EU-EC-10010304951 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Lymphadenopathy (189d - Fatal - **Results in Death**), Renal failure (189d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 9173 | click or scan EU-EC-10010304896 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Delirium (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epistaxis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Faecal vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 9174 | click or scan EU-EC-10010304821 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Unknown - ), Cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9175 | click or scan EU-EC-10010304800 | | 2021-10-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9176 | click or scan EU-EC-10010304647 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 9177 | click or scan EU-EC-10010304605 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9178 | click or scan EU-EC-10010304089 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diabetes mellitus (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphadenopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Swelling (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9179 | click or scan EU-EC-10010304014 | | 2021-10-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9180 | click or scan EU-EC-10010303968 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (6d - Fatal - **Results in Death**), Bacteraemia (6d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (6d - Fatal - **Results in Death**), Hypoxia (6d - Fatal - **Results in Death**, Other Medically Important Condition), Shock (6d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9181 | click or scan EU-EC-10010303900 | | 2021-10-13 | Healthcare Professional | Non EEA | Not Specified | Male | Discomfort (n/a - Unknown - ), Fall (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9182 | click or scan EU-EC-10010303821 | | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9183 | click or scan EU-EC-10010303760 | | 2021-10-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthma (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9184 | click or scan EU-EC-10010303714 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (179d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomyopathy (179d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema (179d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9185 | click or scan EU-EC-10010303437 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lower respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9186 | click or scan EU-EC-10010303307 | | 2021-10-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral artery perforation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral mass effect (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral vascular occlusion (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ventricle collapse (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematoma (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic transformation stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mastoid disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Mucosal hypertrophy (n/a - Unknown - Caused/Prolonged Hospitalisation), Periorbital haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation), Sinusitis (n/a - Unknown - Caused/Prolonged Hospitalisation), White matter lesion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 9187 | click or scan EU-EC-10010303182 | | 2021-10-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | Anaesthetic complication (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9188 | click or scan EU-EC-10010303123 | | 2021-10-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Not Recovered/Not Resolved - ), Cerebrovascular accident (4d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9189 | click or scan EU-EC-10010303072 | | 2021-10-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Diffuse large B-cell lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9190 | click or scan EU-EC-10010303038 | | 2021-10-13 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9191 | click or scan EU-EC-10010302969 | | 2021-10-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9192 | click or scan EU-EC-10010302576 | | 2021-10-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphoria (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9193 | click or scan EU-EC-10010302459 | | 2021-10-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9194 | click or scan EU-EC-10010301656 | | 2021-10-13 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (0d - Fatal - **Results in Death**), Respiratory failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 9195 | click or scan EU-EC-10010300330 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 9196 | click or scan EU-EC-10010299907 | | 2021-10-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9197 | click or scan EU-EC-10010299901 | | 2021-10-12 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9198 | click or scan EU-EC-10010299621 | | 2021-10-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ascites (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chromaturia (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Hallucination (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ), Oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9199 | click or scan EU-EC-10010299604 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral ventricular rupture (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9200 | click or scan EU-EC-10010299041 | | 2021-10-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9201 | click or scan EU-EC-10010299036 | | 2021-10-12 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9202 | click or scan EU-EC-10010298786 |  | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9203 | click or scan EU-EC-10010298661 |  | 2021-10-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| 9204 | click or scan EU-EC-10010298451 |  | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | Asthma (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Hip fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9205 | click or scan EU-EC-10010298337 |  | 2021-10-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9206 | click or scan EU-EC-10010298189 |  | 2021-10-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Restlessness (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9207 | click or scan EU-EC-10010298087 |  | 2021-10-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product administered at inappropriate site (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9208 | click or scan EU-EC-10010297790 |  | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (53d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 9209 | click or scan EU-EC-10010297771 |  | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (162d - Fatal - **Results in Death**), Dyspnoea (162d - Fatal - **Results in Death**), Fatigue (162d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 9210 | click or scan EU-EC-10010297655 |  | 2021-10-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9211 | click or scan EU-EC-10010297350 | | 2021-10-12 | Healthcare Professional | EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9212 | click or scan EU-EC-10010297216 | | 2021-10-12 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Parenteral]) |
| 9213 | click or scan EU-EC-10010297140 | | 2021-10-12 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 9214 | click or scan EU-EC-10010297120 | | 2021-10-12 | Healthcare Professional | EEA | 18-64 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 9215 | click or scan EU-EC-10010297118 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 9216 | click or scan EU-EC-10010297108 | | 2021-10-12 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 9217 | click or scan EU-EC-10010296512 | | 2021-10-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arterial occlusive disease (n/a - Unknown - ), Cardiac disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiovascular disorder (n/a - Unknown - ), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Heat oedema (n/a - Unknown - ), Limb discomfort (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Rash (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9218 | click or scan EU-EC-10010295916 | | 2021-10-12 | Healthcare Professional | EEA | 65-85 Years | Male | Pulseless electrical activity (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9219 | click or scan EU-EC-10010295101 | | 2021-10-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Unknown - ), Arrhythmia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9220 | click or scan EU-EC-10010294946 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9221 | click or scan EU-EC-10010294841 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 9222 | click or scan EU-EC-10010294777 | | 2021-10-12 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9223 | click or scan EU-EC-10010294711 | | 2021-10-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9224 | click or scan EU-EC-10010294328 | | 2021-10-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Blindness (n/a - Unknown - Other Medically Important Condition), Breast cancer (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic cancer (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9225 | click or scan EU-EC-10010294278 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Endotoxic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - **Results in Death**), Salmonellosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9226 | click or scan EU-EC-10010294275 | | 2021-10-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9227 | click or scan EU-EC-10010294257 | | 2021-10-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9228 | click or scan EU-EC-10010294201 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Physical deconditioning (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9229 | click or scan EU-EC-10010293748 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 9230 | click or scan EU-EC-10010293521 | | 2021-10-12 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9231 | click or scan EU-EC-10010292687 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9232 | click or scan EU-EC-10010292642 | | 2021-10-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hot flush (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9233 | click or scan EU-EC-10010292387 | | 2021-10-12 | Healthcare Professional | EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - n/a]) |
| 9234 | click or scan EU-EC-10010292379 | | 2021-10-12 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9235 | click or scan EU-EC-10010292260 | | 2021-10-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute lymphocytic leukaemia (n/a - Fatal - **Results in Death**), Cough (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9236 | click or scan EU-EC-10010291790 | | 2021-10-12 | Healthcare Professional | EEA | 65-85 Years | Female | Malignant neoplasm progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9237 | click or scan EU-EC-10010291572 | | 2021-10-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9238 | click or scan EU-EC-10010291516 | | 2021-10-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9239 | click or scan EU-EC-10010291515 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9240 | click or scan EU-EC-10010291342 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9241** | click or scan EU-EC-10010291267 | | 2021-10-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiopulmonary failure (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **9242** | click or scan EU-EC-10010290956 | | 2021-10-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoptysis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9243** | click or scan EU-EC-10010290600 | | 2021-10-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malignant ascites (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary hypertension (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9244** | click or scan EU-EC-10010290559 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9245** | click or scan EU-EC-10010290219 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**), Pulmonary oedema (1d - Fatal - **Results in Death**, Other Medically Important Condition), Speech disorder (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9246** | click or scan EU-EC-10010290106 | | 2021-10-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Complications of transplant surgery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - ), Dysphonia (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasal congestion (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9247** | click or scan EU-EC-10010290069 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9248** | click or scan EU-EC-10010289820 | | 2021-10-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9249** | click or scan EU-EC-10010289782 | | 2021-10-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9250** | click or scan EU-EC-10010289778 | | 2021-10-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9251** | click or scan EU-EC-10010289748 | | 2021-10-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9252 | click or scan EU-EC-10010289486 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9253 | click or scan EU-EC-10010289485 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9254 | click or scan EU-EC-10010289484 | | 2021-10-12 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9255 | click or scan EU-EC-10010289483 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9256 | click or scan EU-EC-10010289482 | | 2021-10-12 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9257 | click or scan EU-EC-10010288966 | | 2021-10-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 9258 | click or scan EU-EC-10010288717 | | 2021-10-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Unknown - Other Medically Important Condition), Acute respiratory failure (n/a - Unknown - Other Medically Important Condition), Aphasia (5 d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Brain herniation (n/a - Unknown - Other Medically Important Condition), Cough (5 d - Unknown - ), Death (1 d - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (5 d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningioma (n/a - Unknown - Other Medically Important Condition), Osteitis deformans (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (5 d - Unknown - ), Vasogenic cerebral oedema (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9259 | click or scan EU-EC-10010286974 | | 2021-10-12 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (23 d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1 d - 1 {DF} - Intramuscular]) |
| 9260 | click or scan EU-EC-10010286325 | | 2021-10-11 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1 d - n/a - Intramuscular]) |
| 9261 | click or scan EU-EC-10010284292 | | 2021-10-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9262 | click or scan EU-EC-10010283904 | | 2021-10-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Conjunctival haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9263 | click or scan EU-EC-10010283898 | | 2021-10-11 | Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), Colon gangrene (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal perforation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytosis (n/a - Fatal - **Results in Death**), White blood cell count increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9264 | click or scan EU-EC-10010283056 | | 2021-10-11 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Communication disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Eating disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Erythema (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hyporesponsive to stimuli (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Limb injury (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sensory loss (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9265 | click or scan EU-EC-10010282989 | | 2021-10-11 | Non Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9266 | click or scan EU-EC-10010282905 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (2h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 9267 | click or scan EU-EC-10010282888 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (2wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9268 | click or scan EU-EC-10010282863 | | 2021-10-11 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [76d - 3 {DF} - Intramuscular]) |
| 9269 | click or scan EU-EC-10010282799 | | 2021-10-11 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9270 | click or scan EU-EC-10010282736 | | 2021-10-11 | Healthcare Professional | EEA | Not Specified | Male | COVID-19 (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9271** | click or scan EU-EC-10010282677 | | 2021-10-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9272** | click or scan EU-EC-10010282480 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **9273** | click or scan EU-EC-10010282259 | | 2021-10-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9274** | click or scan EU-EC-10010282231 | | 2021-10-11 | Healthcare Professional | EEA | 18-64 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **9275** | click or scan EU-EC-10010281404 | | 2021-10-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyskinesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9276** | click or scan EU-EC-10010281375 | | 2021-10-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral amyloid angiopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal dilatation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial tumour haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis mesenteric vessel (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9277** | click or scan EU-EC-10010281167 | | 2021-10-11 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **9278** | click or scan EU-EC-10010281130 | | 2021-10-11 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9279 | click or scan EU-EC-10010280813 | | 2021-10-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9280 | click or scan EU-EC-10010280812 | | 2021-10-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9281 | click or scan EU-EC-10010280808 | | 2021-10-11 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate abnormal (n/a - Fatal - **Results in Death**), Maternal exposure before pregnancy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 9282 | click or scan EU-EC-10010280781 | | 2021-10-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple sclerosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9283 | click or scan EU-EC-10010280735 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9284 | click or scan EU-EC-10010280734 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9285 | click or scan EU-EC-10010280733 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9286 | click or scan EU-EC-10010280732 | | 2021-10-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9287 | click or scan EU-EC-10010280731 | | 2021-10-11 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9288 | click or scan EU-EC-10010280729 | | 2021-10-11 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9289 | click or scan EU-EC-10010280625 | | 2021-10-11 | Healthcare Professional | EEA | 18-64 Years | Female | Acute leukaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9290 | click or scan EU-EC-10010280571 | | 2021-10-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Brain oedema (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9291 | click or scan EU-EC-10010280404 | | 2021-10-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9292 | click or scan EU-EC-10010280225 | | 2021-10-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9293 | click or scan EU-EC-10010280083 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9294 | click or scan EU-EC-10010279996 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9295 | click or scan EU-EC-10010279115 | | 2021-10-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 9296 | click or scan EU-EC-10010278906 | | 2021-10-11 | Healthcare Professional | EEA | More than 85 Years | Male | Chronic lymphocytic leukaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9297 | click or scan EU-EC-10010278871 | | 2021-10-11 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cytokine release syndrome (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9298 | click or scan EU-EC-10010278765 | | 2021-10-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adenovirus test (n/a - Fatal - **Results in Death**), Arteriosclerosis (n/a - Fatal - **Results in Death**), Autopsy (n/a - Fatal - **Results in Death**), Blood chloride increased (n/a - Fatal - **Results in Death**), Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood glucose decreased (n/a - Fatal - **Results in Death**), Blood potassium increased (n/a - Fatal - **Results in Death**), Blood sodium normal (n/a - Fatal - **Results in Death**), Blood urea increased (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Multipathogen PCR test (n/a - Fatal - **Results in Death**), Platelet factor 4 (n/a - Fatal - **Results in Death**), Pulmonary artery occlusion (n/a - Fatal - **Results in Death**), Respiratory viral panel (n/a - Fatal - **Results in Death**), Toxicologic test abnormal (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9299** | click or scan EU-EC-10010278252 | | 2021-10-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9300** | click or scan EU-EC-10010278188 | | 2021-10-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9301** | click or scan EU-EC-10010278170 | | 2021-10-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9302** | click or scan EU-EC-10010278150 | | 2021-10-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9303** | click or scan EU-EC-10010278123 | | 2021-10-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9304** | click or scan EU-EC-10010278119 | | 2021-10-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9305** | click or scan EU-EC-10010277709 | | 2021-10-11 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **9306** | click or scan EU-EC-10010276627 | | 2021-10-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]), IMBRUVICA [IBRUTINIB] (S - Chronic lymphocytic leukaemia - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9307 | click or scan EU-EC-10010276079 |  | 2021-10-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchospasm (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constipation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Neoplasm progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9308 | click or scan EU-EC-10010275969 |  | 2021-10-11 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9309 | click or scan EU-EC-10010275968 |  | 2021-10-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9310 | click or scan EU-EC-10010275657 |  | 2021-10-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9311 | click or scan EU-EC-10010275452 |  | 2021-10-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9312 | click or scan EU-EC-10010275001 |  | 2021-10-11 | Non Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9313 | click or scan EU-EC-10010273237 |  | 2021-10-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (12d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Coeliac artery stenosis (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colitis (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colitis (5d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - ), Device occlusion (12d - Unknown - ), Diarrhoea (12d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hospitalisation (12d - Fatal - **Results in Death**), Hospitalisation (5d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Renal failure (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Spleen ischaemia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9314 | click or scan EU-EC-10010272828 | | 2021-10-09 | Healthcare Professional | EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9315 | click or scan EU-EC-10010271514 | | 2021-10-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9316 | click or scan EU-EC-10010271505 | | 2021-10-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9317 | click or scan EU-EC-10010271258 | | 2021-10-09 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]) |
| 9318 | click or scan EU-EC-10010271142 | | 2021-10-09 | Non Healthcare Professional | EEA | More than 85 Years | Male | Paralysis (n/a - Fatal - **Results in Death**), Renal impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9319 | click or scan EU-EC-10010271050 | | 2021-10-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (25d - Fatal - **Results in Death**), Cardiac failure (25d - Fatal - **Results in Death**), Dyspnoea (25d - Fatal - **Results in Death**), Oedema (25d - Fatal - **Results in Death**), Pneumonitis (25d - Fatal - **Results in Death**), Respiratory failure (25d - Fatal - **Results in Death**), Sopor (25d - Fatal - **Results in Death**), Urinary tract infection (25d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9320 | click or scan EU-EC-10010270031 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Disease recurrence (n/a - Fatal - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9321 | click or scan EU-EC-10010269681 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (8d - Fatal - **Results in Death**), COVID-19 pneumonia (8d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (8d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (8d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (8d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia streptococcal (8d - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9322 | click or scan EU-EC-10010269576 | | 2021-10-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (2wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomegaly (2wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Incorrect route of product administration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (2wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (2wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Unknown - [14d - 1 {DF} - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 9323 | click or scan EU-EC-10010269446 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9324** | click or scan EU-EC-10010269383 | | 2021-10-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Coagulopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Paraesthesia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vision blurred (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **9325** | click or scan EU-EC-10010269072 | | 2021-10-08 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |
| **9326** | click or scan EU-EC-10010268683 | | 2021-10-08 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Medication error (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9327** | click or scan EU-EC-10010268671 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral mass effect (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9328** | click or scan EU-EC-10010268669 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Facial paralysis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pharyngeal swelling (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9329** | click or scan EU-EC-10010268668 | | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9330** | click or scan EU-EC-10010268417 | | 2021-10-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscle tightness (n/a - Unknown - Other Medically Important Condition), Neoplasm (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Swelling (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9331** | click or scan EU-EC-10010268115 | | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9332 | click or scan EU-EC-10010267953 | | 2021-10-08 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - n/a - Unknown - [1d - n/a - n/a]) |
| 9333 | click or scan EU-EC-10010267704 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**), Physical deconditioning (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9334 | click or scan EU-EC-10010267574 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Volvulus (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9335 | click or scan EU-EC-10010267508 | | 2021-10-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 9336 | click or scan EU-EC-10010267302 | | 2021-10-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anger (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Bipolar disorder (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Completed suicide (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Hostility (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Personality change (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9337 | click or scan EU-EC-10010266989 | | 2021-10-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain upper (n/a - Unknown - ), Aortic aneurysm rupture (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9338 | click or scan EU-EC-10010266893 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9339 | click or scan EU-EC-10010266892 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9340 | click or scan EU-EC-10010266814 | | 2021-10-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cholangitis acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9341 | click or scan EU-EC-10010266810 | | 2021-10-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9342 | click or scan EU-EC-10010266765 | | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 9343 | click or scan EU-EC-10010266757 | | 2021-10-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Herpes zoster (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9344 | click or scan EU-EC-10010266720 | | 2021-10-08 | Healthcare Professional | EEA | 18-64 Years | Male | Obstructive airways disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9345 | click or scan EU-EC-10010266713 | | 2021-10-08 | Healthcare Professional | EEA | 18-64 Years | Male | Venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9346 | click or scan EU-EC-10010266696 | | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]), ZYPREXA 5 MG COATED TABLETS [OLANZAPINE] (S - Depression - Not applicable - [n/a - 5mg - Oral]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (S - Depression - Not applicable - [n/a - 150mg - Oral]) |
| 9347 | click or scan EU-EC-10010266683 | | 2021-10-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9348 | click or scan EU-EC-10010266680 | | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9349 | click or scan EU-EC-10010266645 | | 2021-10-08 | Healthcare Professional | EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9350 | click or scan EU-EC-10010266615 | | 2021-10-08 | Healthcare Professional | EEA | 18-64 Years | Female | Anaplastic thyroid cancer (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9351 | click or scan EU-EC-10010266569 |  | 2021-10-08 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9352 | click or scan EU-EC-10010266528 |  | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cardiac hypertrophy (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Heparin-induced thrombocytopenia test positive (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9353 | click or scan EU-EC-10010266022 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Eyelid haematoma (n/a - Unknown - ), Fall (n/a - Unknown - ), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Orbital swelling (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Swelling (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9354 | click or scan EU-EC-10010266014 |  | 2021-10-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9355 | click or scan EU-EC-10010265639 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9356 | click or scan EU-EC-10010265524 |  | 2021-10-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - 2 {DF} - n/a]) |
| 9357 | click or scan EU-EC-10010265185 |  | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Male | C-reactive protein increased (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Skin discolouration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9358 | click or scan EU-EC-10010265064 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9359 | click or scan EU-EC-10010264519 |  | 2021-10-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9360 | click or scan EU-EC-10010264324 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Alanine aminotransferase increased (n/a - Unknown - ), Albumin globulin ratio decreased (n/a - Unknown - ), Altered state of consciousness (n/a - Fatal - **Results in Death**), Angina pectoris (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aspartate aminotransferase increased (n/a - Unknown - ), Blood alkaline phosphatase increased (n/a - Unknown - ), Blood creatine increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - ), Blood potassium increased (n/a - Unknown - ), Blood pressure immeasurable (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), Brain natriuretic peptide increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardiac valve disease (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Heart rate decreased (n/a - Unknown - ), Hypotension (n/a - Unknown - ), Immunoglobulins increased (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Physical deconditioning (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Protein total decreased (n/a - Unknown - ), Prothrombin time ratio increased (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Troponin T increased (n/a - Unknown - ), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9361 | click or scan EU-EC-10010264151 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bacterial sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9362 | click or scan EU-EC-10010264058 | | 2021-10-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Atherosclerotic plaque rupture (n/a - Fatal - **Results in Death**), Coronary artery occlusion (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 9363 | click or scan EU-EC-10010263980 | | 2021-10-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug interaction (n/a - Unknown - **Results in Death**), Vaccination failure (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (I - n/a - Not applicable - [n/a - n/a - n/a]), [LISINOPRIL, LISINOPRIL ANHYDROUS, LISINOPRIL DIHYDRATE] (I - n/a - Not applicable - [n/a - n/a - Oral]) |
| 9364 | click or scan EU-EC-10010263899 | | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9365 | click or scan EU-EC-10010263884 | | 2021-10-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9366 | click or scan EU-EC-10010263819 | | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Unknown - Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Retching (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9367 | click or scan EU-EC-10010263661 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - ), Diarrhoea (21d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Joint swelling (n/a - Unknown - ), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paralysis (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9368 | click or scan EU-EC-10010263642 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebrovascular disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9369 | click or scan EU-EC-10010263627 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9370 | click or scan EU-EC-10010263565 | | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic kidney disease (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9371 | click or scan EU-EC-10010263353 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9372 | click or scan EU-EC-10010263352 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (11d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9373 | click or scan EU-EC-10010263348 | | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9374 | click or scan EU-EC-10010263347 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9375 | click or scan EU-EC-10010263343 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Throat irritation (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9376 | click or scan EU-EC-10010263322 | | 2021-10-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9377 | click or scan EU-EC-10010263192 | | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 9378 | click or scan EU-EC-10010263016 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9379 | click or scan EU-EC-10010262742 | | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9380 | click or scan EU-EC-10010261704 | | 2021-10-08 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9381 | click or scan EU-EC-10010261082 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anosmia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tonsillitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9382 | click or scan EU-EC-10010260654 | | 2021-10-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal distension (1d - Recovered/Resolved - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Recovered/Resolved - ), Dizziness (n/a - Unknown - ), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Migraine (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Retching (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9383 | click or scan EU-EC-10010260648 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9384 | click or scan EU-EC-10010260602 | | 2021-10-08 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9385 | click or scan EU-EC-10010260531 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Musculoskeletal stiffness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Otitis media (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thunderclap headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9386 | click or scan EU-EC-10010259999 | | 2021-10-08 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Rash (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9387 | click or scan EU-EC-10010259963 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9388 | click or scan EU-EC-10010259866 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thyrotoxic crisis (41d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9389 | click or scan EU-EC-10010259733 | | 2021-10-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9390 | click or scan EU-EC-10010259630 | | 2021-10-08 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9391 | click or scan EU-EC-10010259526 |  | 2021-10-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Erythema (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Head injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Product used for unknown indication - n/a - [n/a - n/a - Intramuscular]), ELIQUIS 5 MG [APIXABAN] (S - Atrial fibrillation - Unknown - [n/a - n/a - Oral]), ELIQUIS [APIXABAN] (S - Cerebrovascular accident prophylaxis - Unknown - [n/a - n/a - Oral]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (S - Atrial fibrillation - Unknown - [n/a - n/a - Oral]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (S - Atrial fibrillation - Unknown - [n/a - n/a - Oral]), [CILOSTAZOL] (S - Arteriosclerosis - Unknown - [n/a - n/a - Oral]), [METHYLPREDNISOLONE] (S - Myalgia - n/a - [n/a - n/a - Unknown]), [ROSUVASTATIN] (S - Arteriosclerosis - Unknown - [n/a - n/a - Oral]) |
| 9392 | click or scan EU-EC-10010259521 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9393 | click or scan EU-EC-10010259455 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9394 | click or scan EU-EC-10010259329 |  | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9395 | click or scan EU-EC-10010259224 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Immunisation (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9396 | click or scan EU-EC-10010259191 |  | 2021-10-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9397 | click or scan EU-EC-10010258974 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9398 | click or scan EU-EC-10010258968 |  | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Skin disorder (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9399 | click or scan EU-EC-10010258634 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9400 | click or scan EU-EC-10010258560 | | 2021-10-08 | Healthcare Professional | EEA | Not Specified | Female | Brain neoplasm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9401 | click or scan EU-EC-10010258504 | | 2021-10-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bradycardia (n/a - Unknown - Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9402 | click or scan EU-EC-10010257688 | | 2021-10-08 | Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9403 | click or scan EU-EC-10010256603 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9404 | click or scan EU-EC-10010256584 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 9405 | click or scan EU-EC-10010256223 | | 2021-10-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (5d - Recovered/Resolved - ), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (5d - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 9406 | click or scan EU-EC-10010255989 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Road traffic accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9407 | click or scan EU-EC-10010255839 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9408 | click or scan EU-EC-10010255773 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9409 | click or scan EU-EC-10010255735 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Blood glucose abnormal (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9410 | click or scan EU-EC-10010255598 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Abdominal pain (2d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Intestinal obstruction (2d - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Unknown - ), Pneumonia (2d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Fatal - **Results in Death**), Sepsis (2d - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 9411 | click or scan EU-EC-10010255347 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9412 | click or scan EU-EC-10010255330 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anisocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coronary artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Right ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9413 | click or scan EU-EC-10010255081 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9414 | click or scan EU-EC-10010254959 | | 2021-10-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Syncope (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vision blurred (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9415 | click or scan EU-EC-10010254881 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9416 | click or scan EU-EC-10010254646 | | 2021-10-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Pain in extremity (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Rash (2d - Fatal - **Results in Death**), Salivary hypersecretion (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9417 | click or scan EU-EC-10010254638 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Hyponatraemia (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9418 | click or scan EU-EC-10010254558 | | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 9419 | click or scan EU-EC-10010254554 | | 2021-10-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Lymphadenopathy (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9420 | click or scan EU-EC-10010254504 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9421 | click or scan EU-EC-10010254414 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9422 | click or scan EU-EC-10010254310 | | 2021-10-07 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9423 | click or scan EU-EC-10010253694 | | 2021-10-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cognitive disorder (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Mental impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Weight decreased (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9424 | click or scan EU-EC-10010253678 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9425 | click or scan EU-EC-10010253650 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9426 | click or scan EU-EC-10010252796 | | 2021-10-07 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9427 | click or scan EU-EC-10010252567 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9428 | click or scan EU-EC-10010252548 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Bile duct cancer (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Ventricular extrasystoles (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9429 | click or scan EU-EC-10010252533 | | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9430 | click or scan EU-EC-10010252530 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9431 | click or scan EU-EC-10010252528 | | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9432 | click or scan EU-EC-10010252506 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [92d - 3 {DF} - Intramuscular]) |
| 9433 | click or scan EU-EC-10010252444 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9434 | click or scan EU-EC-10010252431 | | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [20d - 2 {DF} - Intramuscular]) |
| 9435 | click or scan EU-EC-10010252389 | | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 9436 | click or scan EU-EC-10010252239 | | 2021-10-07 | Healthcare Professional | EEA | Not Specified | Female | Foetal death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal hypokinesia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 9437 | click or scan EU-EC-10010252234 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9438 | click or scan EU-EC-10010252215 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**), Obstructive airways disorder (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9439 | click or scan EU-EC-10010252112 |  | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Disease progression (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - ), Myocardial fibrosis (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9440 | click or scan EU-EC-10010252023 |  | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 9441 | click or scan EU-EC-10010252000 |  | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9442 | click or scan EU-EC-10010251933 |  | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Immunisation (n/a - Unknown - ), Off label use (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9443 | click or scan EU-EC-10010251852 |  | 2021-10-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Illness (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9444 | click or scan EU-EC-10010251834 |  | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Schizophrenia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9445 | click or scan EU-EC-10010251624 |  | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9446 | click or scan EU-EC-10010251543 |  | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9447 | click or scan EU-EC-10010251212 |  | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9448 | click or scan EU-EC-10010251167 |  | 2021-10-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9449 | click or scan EU-EC-10010251101 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pleural effusion (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9450 | click or scan EU-EC-10010251051 | | 2021-10-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Altered state of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Unknown]) |
| 9451 | click or scan EU-EC-10010250744 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperkalaemia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Stertor (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9452 | click or scan EU-EC-10010250706 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9453 | click or scan EU-EC-10010250702 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9454 | click or scan EU-EC-10010250685 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pancytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9455 | click or scan EU-EC-10010250653 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 9456 | click or scan EU-EC-10010249977 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9457 | click or scan EU-EC-10010249665 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Lividity (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Vaccination site discolouration (n/a - Fatal - **Results in Death**), Vaccination site reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9458 | click or scan EU-EC-10010249517 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9459 | click or scan EU-EC-10010249507 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9460 | click or scan EU-EC-10010249501 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9461 | click or scan EU-EC-10010249414 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (71d - Fatal - **Results in Death**), Escherichia infection (71d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9462 | click or scan EU-EC-10010249182 | | 2021-10-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 9463 | click or scan EU-EC-10010248871 | | 2021-10-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9464 | click or scan EU-EC-10010248217 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9465 | click or scan EU-EC-10010248212 | | 2021-10-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Immunisation (n/a - Unknown - ), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9466 | click or scan EU-EC-10010248208 | | 2021-10-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9467 | click or scan EU-EC-10010248195 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9468 | click or scan EU-EC-10010248018 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9469 | click or scan EU-EC-10010248015 |  | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Ileus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Insomnia (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9470 | click or scan EU-EC-10010247964 |  | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (9d - Fatal - **Results in Death**), Malaise (9d - Fatal - **Results in Death**), Somnolence (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 9471 | click or scan EU-EC-10010247914 |  | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (10d - Fatal - **Results in Death**), Dyspnoea exertional (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 9472 | click or scan EU-EC-10010247900 |  | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9473 | click or scan EU-EC-10010247894 |  | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9474 | click or scan EU-EC-10010247597 |  | 2021-10-07 | Healthcare Professional | EEA | 18-64 Years | Male | Acute abdomen (46d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Anastomotic complication (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood product transfusion dependent (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal ischaemia (46d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Shock haemorrhagic (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 9475 | click or scan EU-EC-10010247567 |  | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9476 | click or scan EU-EC-10010247425 |  | 2021-10-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 9477 | click or scan EU-EC-10010247323 |  | 2021-10-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Furuncle (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9478** | click or scan<br>EU-EC-10010247243 | | 2021-10-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin discolouration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **9479** | click or scan<br>EU-EC-10010247090 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic valve sclerosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchial haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic steatosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung induration (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mucosal haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1mL - Intramuscular]) |
| **9480** | click or scan<br>EU-EC-10010247023 | | 2021-10-07 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9481 | click or scan EU-EC-10010246991 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Alanine aminotransferase increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cold sweat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Contusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastroenteritis viral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrointestinal oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Musculoskeletal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Photophobia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Portal vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Purpura (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Viral infection (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9482 | click or scan EU-EC-10010246857 | | 2021-10-07 | Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9483 | click or scan EU-EC-10010246809 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9484 | click or scan EU-EC-10010246803 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9485 | click or scan EU-EC-10010246755 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral mass effect (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nausea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Superior sagittal sinus thrombosis (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9486 | click or scan EU-EC-10010246744 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9487 | click or scan EU-EC-10010246568 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial flutter (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9488 | click or scan EU-EC-10010246470 | | 2021-10-07 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac death (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9489 | click or scan EU-EC-10010246268 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9490 | click or scan EU-EC-10010245974 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation), Stertor (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9491 | click or scan EU-EC-10010245957 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9492 | click or scan EU-EC-10010245693 | | 2021-10-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Eating disorder (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9493 | click or scan EU-EC-10010245097 | | 2021-10-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9494 | click or scan EU-EC-10010243318 | | 2021-10-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Illness (n/a - Unknown - ), Influenza like illness (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9495 | click or scan EU-EC-10010243245 | | 2021-10-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthma (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - ), Sputum retention (n/a - Unknown - ), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9496 | click or scan EU-EC-10010243178 | | 2021-10-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9497 | click or scan EU-EC-10010243012 | | 2021-10-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9498 | click or scan EU-EC-10010243010 | | 2021-10-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9499 | click or scan EU-EC-10010242985 | | 2021-10-07 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic stenosis (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 9500 | click or scan EU-EC-10010242945 | | 2021-10-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9501 | click or scan EU-EC-10010242762 | | 2021-10-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9502 | click or scan EU-EC-10010244461 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9503 | click or scan EU-EC-10010244082 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arteriosclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Coeliac artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Grimacing (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ileus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric arterial occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mydriasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9504 | click or scan EU-EC-10010244027 | | 2021-10-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9505 | click or scan EU-EC-10010244018 | | 2021-10-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9506** | click or scan EU-EC-10010244016 | | 2021-10-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| **9507** | click or scan EU-EC-10010243985 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9508** | click or scan EU-EC-10010243656 | | 2021-10-06 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9509** | click or scan EU-EC-10010243633 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Immune thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myocardial strain imaging (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory tract infection (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9510** | click or scan EU-EC-10010243611 | | 2021-10-06 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **9511** | click or scan EU-EC-10010243579 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Female | Loss of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9512** | click or scan EU-EC-10010243550 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - ), Intracranial pressure increased (n/a - Unknown - Other Medically Important Condition), Stupor (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **9513** | click or scan EU-EC-10010242606 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (55d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Creutzfeldt-Jakob disease (4d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (108d - Unknown - Caused/Prolonged Hospitalisation), Insomnia (108d - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9514 | click or scan EU-EC-10010242071 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9515 | click or scan EU-EC-10010241884 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (3d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drooling (3d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (3d - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (3d - Unknown - Other Medically Important Condition), Myocardial infarction (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9516 | click or scan EU-EC-10010241862 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9517 | click or scan EU-EC-10010241835 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Dyspnoea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9518 | click or scan EU-EC-10010241717 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Extra dose administered (n/a - Unknown - Caused/Prolonged Hospitalisation), Stress cardiomyopathy (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9519 | click or scan EU-EC-10010240779 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain lower (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acidosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anuria (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetes mellitus (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dialysis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal inflammation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal wall thickening (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodynamic instability (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Obesity (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancreatitis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Slow response to stimuli (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vascular calcification (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9520 | click or scan EU-EC-10010240736 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (5d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9521 | click or scan EU-EC-10010240371 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic kidney disease (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9522 | click or scan EU-EC-10010239652 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9523 | click or scan EU-EC-10010239636 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (43d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9524 | click or scan EU-EC-10010239574 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening), Syncope (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9525 | click or scan EU-EC-10010239509 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), RITUXIMAB [RITUXIMAB] (S - Multifocal motor neuropathy - n/a - [1d - 500mg - n/a]), [HUMAN NORMAL IMMUNOGLOBULIN, HUMAN NORMAL IMMUNOGLOBULIN (IV), IMMUNOGLOBULIN G] (S - Multifocal motor neuropathy - n/a - [1d - 60g - n/a]) |
| 9526 | click or scan EU-EC-10010239172 | | 2021-10-06 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular]) |
| 9527 | click or scan EU-EC-10010239171 | | 2021-10-06 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular]) |
| 9528 | click or scan EU-EC-10010239167 | | 2021-10-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9529 | click or scan EU-EC-10010239137 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| 9530 | click or scan EU-EC-10010239134 | | 2021-10-06 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9531 | click or scan EU-EC-10010239119 | | 2021-10-06 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| 9532 | click or scan EU-EC-10010239092 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 9533 | click or scan EU-EC-10010239032 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Female | Peripheral ischaemia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9534 | click or scan EU-EC-10010238567 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Melaena (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9535 | click or scan EU-EC-10010238058 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9536 | click or scan EU-EC-10010237992 | | 2021-10-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9537 | click or scan EU-EC-10010237983 | | 2021-10-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9538 | click or scan EU-EC-10010237872 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9539 | click or scan EU-EC-10010237756 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cystitis noninfective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 9540 | click or scan EU-EC-10010237643 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9541 | click or scan EU-EC-10010237512 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory distress (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9542 | click or scan EU-EC-10010237454 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Amyotrophic lateral sclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9543 | click or scan EU-EC-10010237401 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9544 | click or scan EU-EC-10010237065 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Gait inability (n/a - Unknown - Other Medically Important Condition), Terminal state (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9545 | click or scan EU-EC-10010236692 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Female | Epilepsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperpyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9546 | click or scan EU-EC-10010236689 | | 2021-10-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9547 | click or scan EU-EC-10010236621 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9548 | click or scan EU-EC-10010236497 | | 2021-10-06 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (5d - Fatal - **Results in Death**), Atrial fibrillation (3d - Fatal - **Results in Death**), Cholestasis (1d - Fatal - **Results in Death**), Cyanosis (3d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Delirium (2d - Fatal - **Results in Death**), Dyspnoea at rest (5d - Fatal - **Results in Death**), Hypotension (3d - Fatal - **Results in Death**), Lactic acidosis (2d - Fatal - **Results in Death**), Myalgia (5d - Fatal - **Results in Death**), Oliguria (1d - Fatal - **Results in Death**), Oxygen saturation decreased (3d - Fatal - **Results in Death**), Renal failure (1d - Fatal - **Results in Death**), Respiratory distress (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9549 | click or scan EU-EC-10010236496 | | 2021-10-06 | Healthcare Professional | EEA | 18-64 Years | Female | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9550 | click or scan EU-EC-10010236311 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous thrombosis (3d - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma scale abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Superior sagittal sinus thrombosis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9551 | click or scan EU-EC-10010236305 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9552 | click or scan EU-EC-10010236276 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9553 | click or scan EU-EC-10010236244 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9554 | click or scan EU-EC-10010236124 | | 2021-10-06 | Healthcare Professional | EEA | 18-64 Years | Female | Chills (2d - Recovered/Resolved - ), Malaise (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9555 | click or scan EU-EC-10010236022 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiovascular disorder (0d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9556 | click or scan EU-EC-10010235991 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 9557 | click or scan EU-EC-10010235952 | | 2021-10-06 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 9558 | click or scan EU-EC-10010235881 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 9559 | click or scan EU-EC-10010235620 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 9560 | click or scan EU-EC-10010235571 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aphasia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous thrombosis (3d - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Superior sagittal sinus thrombosis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9561 | click or scan EU-EC-10010235484 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute chest syndrome (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Crepitations (n/a - Fatal - **Results in Death**), Deafness neurosensory (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hyperlactacidaemia (n/a - Fatal - **Results in Death**), Hypoglycaemia (n/a - Fatal - **Results in Death**), Hypokalaemia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Metabolic acidosis (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary hypertension (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Sickle cell disease (n/a - Fatal - **Results in Death**), Sinus tachycardia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9562 | click or scan EU-EC-10010235474 | | 2021-10-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9563 | click or scan EU-EC-10010235408 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Gastric haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic cirrhosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9564 | click or scan EU-EC-10010235394 | | 2021-10-06 | Healthcare Professional | EEA | Not Specified | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9565 | click or scan EU-EC-10010235166 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9566 | click or scan EU-EC-10010235080 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Incontinence (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pollakiuria (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine abnormality (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9567 | click or scan EU-EC-10010235014 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung consolidation (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung opacity (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9568 | click or scan EU-EC-10010234954 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9569 | click or scan EU-EC-10010234909 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9570 | click or scan EU-EC-10010234862 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9571 | click or scan EU-EC-10010234854 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9572** | click or scan EU-EC-10010234722 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **9573** | click or scan EU-EC-10010234458 | | 2021-10-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9574** | click or scan EU-EC-10010234387 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Atrioventricular block (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9575** | click or scan EU-EC-10010234362 | | 2021-10-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9576** | click or scan EU-EC-10010234334 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Jaundice (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9577** | click or scan EU-EC-10010234227 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic valve replacement (n/a - Fatal - **Results in Death**), Cardiac procedure complication (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9578** | click or scan EU-EC-10010234048 | | 2021-10-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (10d - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **9579** | click or scan EU-EC-10010233952 | | 2021-10-06 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection bacterial (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **9580** | click or scan EU-EC-10010233798 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9581** | click or scan EU-EC-10010233625 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inflammatory bowel disease (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9582 | click or scan EU-EC-10010233389 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9583 | click or scan EU-EC-10010233370 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (34d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (34d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (34d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (34d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (34d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9584 | click or scan EU-EC-10010233369 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9585 | click or scan EU-EC-10010233269 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to contaminated air (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9586 | click or scan EU-EC-10010233192 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoglycaemic coma (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9587 | click or scan EU-EC-10010233124 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), End stage renal disease (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemodialysis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypervolaemia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9588 | click or scan EU-EC-10010233123 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ascites (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cardiogenic shock (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Congestive hepatopathy (n/a - Unknown - Other Medically Important Condition), Hepatic failure (n/a - Unknown - Other Medically Important Condition), Hepatomegaly (n/a - Unknown - ), Hyperventilation (n/a - Unknown - ), Inflammation (n/a - Unknown - ), Metabolic acidosis (n/a - Unknown - ), Myocarditis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Renal disorder (n/a - Unknown - ), Renal failure (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9589 | click or scan EU-EC-10010233122 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Extra dose administered (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Feeling abnormal (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9590 | click or scan EU-EC-10010233033 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9591 | click or scan EU-EC-10010233031 | | 2021-10-06 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 9592 | click or scan EU-EC-10010233017 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9593 | click or scan EU-EC-10010233014 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9594 | click or scan EU-EC-10010232967 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9595 | click or scan EU-EC-10010232925 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9596 | click or scan EU-EC-10010232889 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest discomfort (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9597 | click or scan EU-EC-10010232787 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Poor quality sleep (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9598 | click or scan EU-EC-10010232782 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), End stage renal disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9599 | click or scan EU-EC-10010232776 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9600 | click or scan EU-EC-10010232736 | | 2021-10-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9601** | click or scan EU-EC-10010232731 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Movement disorder (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9602** | click or scan EU-EC-10010232693 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9603** | click or scan EU-EC-10010232564 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9604** | click or scan EU-EC-10010232492 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9605** | click or scan EU-EC-10010232458 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9606** | click or scan EU-EC-10010232410 | | 2021-10-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9607** | click or scan EU-EC-10010232292 | | 2021-10-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Dyspnoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nephropathy (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9608** | click or scan EU-EC-10010232117 | | 2021-10-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9609** | click or scan EU-EC-10010230191 | | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Female | Bacterial infection (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal infection (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9610 | click or scan EU-EC-10010230173 |  | 2021-10-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem stroke (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9611 | click or scan EU-EC-10010229791 |  | 2021-10-05 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9612 | click or scan EU-EC-10010228982 |  | 2021-10-05 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic embolus (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Painful respiration (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Dose not changed - [n/a - 1 {DF} - Intramuscular]) |
| 9613 | click or scan EU-EC-10010228740 |  | 2021-10-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9614 | click or scan EU-EC-10010228143 |  | 2021-10-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9615 | click or scan EU-EC-10010228083 |  | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9616 | click or scan EU-EC-10010227832 |  | 2021-10-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9617 | click or scan EU-EC-10010227795 |  | 2021-10-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 9618 | click or scan EU-EC-10010227690 |  | 2021-10-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Aphasia (n/a - Fatal - **Results in Death**), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Monoplegia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Partial seizures (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9619 | click or scan EU-EC-10010227670 | | 2021-10-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9620 | click or scan EU-EC-10010227381 | | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Male | Congestive cardiomyopathy (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9621 | click or scan EU-EC-10010227322 | | 2021-10-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dry mouth (n/a - Unknown - ), Palpitations (n/a - Unknown - ), Toxic shock syndrome (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9622 | click or scan EU-EC-10010227239 | | 2021-10-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Recovering/Resolving - ), Ventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9623 | click or scan EU-EC-10010226915 | | 2021-10-05 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9624 | click or scan EU-EC-10010226901 | | 2021-10-05 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9625 | click or scan EU-EC-10010226871 | | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9626 | click or scan EU-EC-10010226554 | | 2021-10-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9627 | click or scan EU-EC-10010226525 | | 2021-10-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aspiration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9628 | click or scan EU-EC-10010225675 | | 2021-10-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acidosis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (32d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Life Threatening, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Life Threatening, Other Medically Important Condition), Resuscitation (n/a - Unknown - Life Threatening, Other Medically Important Condition), Seizure (n/a - Unknown - Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9629 | click or scan EU-EC-10010225171 | | 2021-10-05 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [182d - 1{DF} - Intramuscular]) |
| 9630 | click or scan EU-EC-10010225147 | | 2021-10-05 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 9631 | click or scan EU-EC-10010225140 | | 2021-10-05 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 9632 | click or scan EU-EC-10010225103 | | 2021-10-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9633 | click or scan EU-EC-10010224752 | | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Recovering/Resolving - ), Chest pain (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Flank pain (n/a - Not Recovered/Not Resolved - ), Malaise (2d - Recovered/Resolved - ), Myocarditis (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 9634 | click or scan EU-EC-10010224697 | | 2021-10-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Confusional state (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 9635 | click or scan EU-EC-10010224508 | | 2021-10-05 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 9636 | click or scan EU-EC-10010224444 | | 2021-10-05 | Healthcare Professional | EEA | Not Specified | Male | Brain injury (n/a - Fatal - **Results in Death**), Exposure during pregnancy (n/a - Fatal - **Results in Death**), Neonatal asphyxia (n/a - Fatal - **Results in Death**), Premature baby (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 9637 | click or scan EU-EC-10010224212 | | 2021-10-05 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Escherichia test positive (n/a - Unknown - ), Lethargy (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Nitrite urine present (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Red blood cells urine positive (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9638 | click or scan EU-EC-10010224211 | | 2021-10-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ataxia (n/a - Not Recovered/Not Resolved - ), Cerebral arteriosclerosis (n/a - Unknown - ), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyslalia (n/a - Not Recovered/Not Resolved - ), Dysphagia (n/a - Not Recovered/Not Resolved - ), Gait disturbance (n/a - Not Recovered/Not Resolved - ), Irregular breathing (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**), Thrombotic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9639 | click or scan EU-EC-10010224202 | | 2021-10-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9640 | click or scan EU-EC-10010223769 | | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**), Palpitations (20d - Fatal - **Results in Death**), Panic disorder (20d - Fatal - **Results in Death**), Sinus tachycardia (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9641 | click or scan EU-EC-10010223144 | | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9642 | click or scan EU-EC-10010222691 | | 2021-10-05 | Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening), Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening), Inflammatory marker increased (n/a - Not Recovered/Not Resolved - Life Threatening), Pericarditis (n/a - Fatal - **Results in Death**, Life Threatening), Pleural effusion (n/a - Not Recovered/Not Resolved - Life Threatening), Somnolence (n/a - Not Recovered/Not Resolved - Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9643 | click or scan EU-EC-10010222393 | | 2021-10-05 | Non Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9644 | click or scan EU-EC-10010221411 | | 2021-10-05 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Ketoacidosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9645 | click or scan EU-EC-10010220879 | | 2021-10-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Incorrect route of product administration (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous]) |
| 9646 | click or scan EU-EC-10010220547 | | 2021-10-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Constipation (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Urinary tract infection (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9647 | click or scan EU-EC-10010220544 | | 2021-10-05 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9648 | click or scan EU-EC-10010220538 | | 2021-10-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9649** | click or scan EU-EC-10010220192 | | 2021-10-05 | Healthcare Professional | EEA | More than 85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9650** | click or scan EU-EC-10010219783 | | 2021-10-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiomyopathy (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9651** | click or scan EU-EC-10010219421 | | 2021-10-05 | Non Healthcare Professional | Non EEA | Not Specified | Female | Palpitations (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9652** | click or scan EU-EC-10010219058 | | 2021-10-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition), Swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9653** | click or scan EU-EC-10010218614 | | 2021-10-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Encephalitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9654** | click or scan EU-EC-10010218209 | | 2021-10-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9655** | click or scan EU-EC-10010218000 | | 2021-10-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9656** | click or scan EU-EC-10010217967 | | 2021-10-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9657 | click or scan EU-EC-10010217729 | | 2021-10-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal infarct (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Splenic infarction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular extrasystoles (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9658 | click or scan EU-EC-10010217287 | | 2021-10-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9659 | click or scan EU-EC-10010217101 | | 2021-10-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - ), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9660 | click or scan EU-EC-10010216583 | | 2021-10-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9661 | click or scan EU-EC-10010216477 | | 2021-10-05 | Non Healthcare Professional | EEA | Not Specified | Female | Inappropriate schedule of product administration (n/a - Unknown - ), Mineral metabolism disorder (1wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasms (1wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (1wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9662 | click or scan EU-EC-10010214548 | | 2021-10-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Memory impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 9663 | click or scan EU-EC-10010214450 | | 2021-10-04 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9664 | click or scan EU-EC-10010214398 | | 2021-10-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9665 | click or scan EU-EC-10010214182 | | 2021-10-04 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 9666 | click or scan EU-EC-10010213952 | | 2021-10-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9667 | click or scan EU-EC-10010213893 | | 2021-10-04 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9668 | click or scan EU-EC-10010213756 | | 2021-10-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Unknown - [n/a - n/a - Intramuscular]) |
| 9669 | click or scan EU-EC-10010213610 | | 2021-10-04 | Healthcare Professional | Non EEA | Not Specified | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9670 | click or scan EU-EC-10010213161 | | 2021-10-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9671 | click or scan EU-EC-10010213106 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Aortic stenosis (n/a - Fatal - **Results in Death**), Colitis ischaemic (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9672 | click or scan EU-EC-10010213103 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9673** | click or scan EU-EC-10010212090 | | 2021-10-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9674** | click or scan EU-EC-10010211541 | | 2021-10-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **9675** | click or scan EU-EC-10010211319 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9676** | click or scan EU-EC-10010211317 | | 2021-10-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (1d - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9677** | click or scan EU-EC-10010210960 | | 2021-10-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Constipation (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **9678** | click or scan EU-EC-10010210617 | | 2021-10-04 | Healthcare Professional | EEA | More than 85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **9679** | click or scan EU-EC-10010210611 | | 2021-10-04 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **9680** | click or scan EU-EC-10010210610 | | 2021-10-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Therapeutic response decreased (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9681** | click or scan EU-EC-10010210606 | | 2021-10-04 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **9682** | click or scan EU-EC-10010210576 | | 2021-10-04 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **9683** | click or scan EU-EC-10010210538 | | 2021-10-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9684 | click or scan EU-EC-10010210458 | | 2021-10-04 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9685 | click or scan EU-EC-10010210450 | | 2021-10-04 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 9686 | click or scan EU-EC-10010210326 | | 2021-10-04 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9687 | click or scan EU-EC-10010209585 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9688 | click or scan EU-EC-10010208957 | | 2021-10-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**), Gastric ulcer haemorrhage (n/a - Fatal - **Results in Death**), Shock haemorrhagic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9689 | click or scan EU-EC-10010208830 | | 2021-10-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9690 | click or scan EU-EC-10010208820 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased activity (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9691 | click or scan EU-EC-10010208806 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9692 | click or scan EU-EC-10010208787 | | 2021-10-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**), Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9693 | click or scan EU-EC-10010208571 | | 2021-10-04 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9694 | click or scan EU-EC-10010207895 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9695 | click or scan EU-EC-10010207745 | | 2021-10-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Brain stem infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | ANTICOAGULANS (BLOEDVERDUNNER) [NOT AVAILABLE] (S - Product used for unknown indication - Drug withdrawn - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9696 | click or scan EU-EC-10010207541 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9697 | click or scan EU-EC-10010206746 | | 2021-10-04 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Cerebral infarction (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 9698 | click or scan EU-EC-10010206468 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Unknown - Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Unknown - ), Atelectasis (n/a - Unknown - ), Atypical pneumonia (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - ), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiac failure congestive (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Goitre (n/a - Unknown - ), Hypervolaemia (n/a - Unknown - ), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition), Lung consolidation (n/a - Unknown - ), Lung infiltration (n/a - Unknown - ), Lung opacity (n/a - Unknown - ), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - ), Pneumomediastinum (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pneumothorax (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Subcutaneous emphysema (n/a - Unknown - ), Superficial vein thrombosis (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition), Thyroid calcification (n/a - Unknown - ), Vascular calcification (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9699 | click or scan EU-EC-10010206446 | | 2021-10-04 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure decreased (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Feeling abnormal (0d - Fatal - **Results in Death**), Hypoaesthesia oral (0d - Fatal - **Results in Death**), Seizure (0d - Fatal - **Results in Death**), Sluggishness (0d - Fatal - **Results in Death**), Tonic convulsion (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 9700 | click or scan EU-EC-10010206068 | | 2021-10-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9701 | click or scan EU-EC-10010206005 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anuria (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Generalised oedema (n/a - Unknown - Other Medically Important Condition), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Hypokalaemia (n/a - Unknown - Other Medically Important Condition), Liver disorder (n/a - Unknown - Other Medically Important Condition), Malnutrition (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Respiratory alkalosis (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Weight increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [EDARAVONE] (S - Cerebral infarction - Unknown - [n/a - 60mg - n/a]), [PAZUFLOXACIN MESILATE] (S - n/a - Unknown - [n/a - 1g - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9702 | click or scan EU-EC-10010206003 | | 2021-10-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9703 | click or scan EU-EC-10010205989 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9704 | click or scan EU-EC-10010205541 | | 2021-10-04 | Healthcare Professional | EEA | 18-64 Years | Female | Ruptured cerebral aneurysm (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9705 | click or scan EU-EC-10010205490 | | 2021-10-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9706 | click or scan EU-EC-10010205461 | | 2021-10-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Colon cancer metastatic (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9707 | click or scan EU-EC-10010205251 | | 2021-10-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 9708 | click or scan EU-EC-10010205229 | | 2021-10-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - **Results in Death**), Thrombocytopenic purpura (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9709 | click or scan EU-EC-10010204416 | | 2021-10-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9710 | click or scan EU-EC-10010203960 | | 2021-10-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Localised infection (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), [ENZALUTAMIDE] (S - Prostate cancer - Not applicable - [302d - 160mg - Oral]) |
| 9711 | click or scan EU-EC-10010203748 | | 2021-10-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood blister (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Epistaxis (n/a - Recovered/Resolved - Other Medically Important Condition), Haematemesis (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Petechiae (n/a - Unknown - Other Medically Important Condition), Rhinitis (n/a - Recovered/Resolved - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9712 | click or scan EU-EC-10010203718 | | 2021-10-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9713 | click or scan EU-EC-10010201118 | | 2021-10-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dermatitis bullous (n/a - Fatal - **Results in Death**), Skin lesion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 9714 | click or scan EU-EC-10010200992 | | 2021-10-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Sneezing (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 9715 | click or scan EU-EC-10010200987 | | 2021-10-02 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (3d - Fatal - **Results in Death**), Drug ineffective (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 9716 | click or scan EU-EC-10010200564 | | 2021-10-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (2d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 9717 | click or scan EU-EC-10010199120 | | 2021-10-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9718 | click or scan EU-EC-10010200399 | | 2021-10-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9719 | click or scan EU-EC-10010200285 | | 2021-10-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Haematemesis (0d - Fatal - **Results in Death**), Upper gastrointestinal haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9720 | click or scan EU-EC-10010200283 | | 2021-10-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9721 | click or scan EU-EC-10010200276 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9722 | click or scan EU-EC-10010200095 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9723 | click or scan EU-EC-10010199951 | | 2021-10-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9724 | click or scan EU-EC-10010199923 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9725 | click or scan EU-EC-10010199555 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug interaction (n/a - Unknown - ), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fluid intake reduced (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [CANDESARTAN CILEXETIL] (I - n/a - Not applicable - [n/a - n/a - Oral]), [DILTIAZEM HYDROCHLORIDE] (I - n/a - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]), [SPIRONOLACTONE] (I - n/a - Not applicable - [n/a - n/a - n/a]), [WARFARIN SODIUM] (I - n/a - Not applicable - [n/a - n/a - n/a]) |
| 9726 | click or scan EU-EC-10010198720 | | 2021-10-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Foetal hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 9727 | click or scan EU-EC-10010198709 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Hyperplasia (n/a - Fatal - **Results in Death**), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9728 | click or scan EU-EC-10010198677 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 9729 | click or scan EU-EC-10010198342 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9730 | click or scan EU-EC-10010198338 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasopharyngitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9731 | click or scan EU-EC-10010198201 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9732 | click or scan EU-EC-10010197986 | | 2021-10-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyslexia (n/a - Unknown - Other Medically Important Condition), Intellectual disability (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ), Mental disorder (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - ), Retinal degeneration (n/a - Unknown - Other Medically Important Condition), Retinal detachment (n/a - Unknown - Other Medically Important Condition), Retinal tear (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9733 | click or scan EU-EC-10010197982 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9734 | click or scan EU-EC-10010197783 | | 2021-10-01 | Healthcare Professional | EEA | 18-64 Years | Male | Cavernous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 9735 | click or scan EU-EC-10010197233 | | 2021-10-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9736 | click or scan EU-EC-10010196652 | | 2021-10-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9737 | click or scan EU-EC-10010196494 | | 2021-10-01 | Non Healthcare Professional | EEA | Not Specified | Male | Embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9738 | click or scan EU-EC-10010196187 | | 2021-10-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9739 | click or scan EU-EC-10010195890 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9740 | click or scan EU-EC-10010195770 | | 2021-10-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (11d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (11d - Unknown - Other Medically Important Condition), Pyrexia (11d - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9741 | click or scan EU-EC-10010195640 |  | 2021-10-01 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9742 | click or scan EU-EC-10010195631 |  | 2021-10-01 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9743 | click or scan EU-EC-10010195557 |  | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9744 | click or scan EU-EC-10010195552 |  | 2021-10-01 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9745 | click or scan EU-EC-10010195537 |  | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Male | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [D,L-LYSINE ACETYLSALICYLATE] (S - Thrombosis prophylaxis - Not applicable - [n/a - 75mg - Oral]) |
| 9746 | click or scan EU-EC-10010195522 |  | 2021-10-01 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 9747 | click or scan EU-EC-10010195455 |  | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [40d - 2{DF} - Intramuscular]) |
| 9748 | click or scan EU-EC-10010195453 |  | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (27d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1{DF} - Intramuscular]) |
| 9749 | click or scan EU-EC-10010195444 |  | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 9750 | click or scan EU-EC-10010195329 |  | 2021-10-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9751 | click or scan EU-EC-10010195249 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Joint effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9752 | click or scan EU-EC-10010195036 | | 2021-10-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Chronic obstructive pulmonary disease (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Joint stiffness (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Malaise (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9753 | click or scan EU-EC-10010195025 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9754 | click or scan EU-EC-10010194695 | | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiomegaly (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 9755 | click or scan EU-EC-10010194313 | | 2021-10-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9756 | click or scan EU-EC-10010194252 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Unknown - ), Chronic respiratory failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9757 | click or scan EU-EC-10010193874 | | 2021-10-01 | Non Healthcare Professional | EEA | 18-64 Years | Female | Chills (5d - Recovered/Resolved - ), Hyperhidrosis (5d - Recovered/Resolved - ), Pulmonary embolism (7d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9758 | click or scan EU-EC-10010193649 | | 2021-10-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9759 | click or scan EU-EC-10010192809 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9760 | click or scan EU-EC-10010192671 | | 2021-10-01 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9761** | click or scan EU-EC-10010192351 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ileus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9762** | click or scan EU-EC-10010192098 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [DONEPEZIL] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]) |
| **9763** | click or scan EU-EC-10010192036 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **9764** | click or scan EU-EC-10010191908 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (1d - Recovered/Resolved - Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9765** | click or scan EU-EC-10010191135 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9766** | click or scan EU-EC-10010191039 | | 2021-10-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9767** | click or scan EU-EC-10010190920 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9768** | click or scan EU-EC-10010190815 | | 2021-10-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Autoimmune disorder (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9769** | click or scan EU-EC-10010190146 | | 2021-10-01 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9770** | click or scan EU-EC-10010190135 | | 2021-10-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9771 | click or scan EU-EC-10010189900 | | 2021-10-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9772 | click or scan EU-EC-10010189732 | | 2021-10-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Unknown - ), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Oxygen saturation decreased (n/a - Unknown - ), Pain (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9773 | click or scan EU-EC-10010189706 | | 2021-10-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9774 | click or scan EU-EC-10010189571 | | 2021-10-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9775 | click or scan EU-EC-10010189516 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9776 | click or scan EU-EC-10010189490 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9777 | click or scan EU-EC-10010189485 | | 2021-10-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9778 | click or scan EU-EC-10010189266 | | 2021-10-01 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (5d - Fatal - **Results in Death**), Drug ineffective (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 9779 | click or scan EU-EC-10010189190 | | 2021-10-01 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 9780 | click or scan EU-EC-10010189185 | | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (29d - Fatal - **Results in Death**), Groin pain (29d - Fatal - **Results in Death**), Leukopenia (29d - Fatal - **Results in Death**), Septic shock (29d - Fatal - **Results in Death**), Thrombocytopenia (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9781** | click or scan EU-EC-10010187346 | | 2021-10-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Ischaemia (n/a - Fatal - **Results in Death**), Retching (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **9782** | click or scan EU-EC-10010187326 | | 2021-10-01 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **9783** | click or scan EU-EC-10010187325 | | 2021-10-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Back pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **9784** | click or scan EU-EC-10010187304 | | 2021-10-01 | Healthcare Professional | EEA | More than 85 Years | Male | Agitation (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**), Somnolence (0d - Fatal - **Results in Death**), Tachypnoea (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **9785** | click or scan EU-EC-10010187957 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Carbon monoxide poisoning (n/a - Fatal - **Results in Death**), Cervical vertebral fracture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Rib fracture (n/a - Fatal - **Results in Death**), Spinal cord haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9786** | click or scan EU-EC-10010187739 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Eye pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Neurosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9787** | click or scan EU-EC-10010187052 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (2d - Fatal - **Results in Death**), Tremor (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9788** | click or scan EU-EC-10010186973 | | 2021-09-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9789** | click or scan EU-EC-10010186945 | | 2021-09-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9790** | click or scan EU-EC-10010186885 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhagic adrenal infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9791** | click or scan EU-EC-10010186836 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pseudomonas infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9792** | click or scan EU-EC-10010186690 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| **9793** | click or scan EU-EC-10010185826 | | 2021-09-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **9794** | click or scan EU-EC-10010185010 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9795** | click or scan EU-EC-10010185001 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9796** | click or scan EU-EC-10010182745 | | 2021-09-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9797** | click or scan EU-EC-10010182709 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9798** | click or scan EU-EC-10010181500 | | 2021-09-30 | Healthcare Professional | EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **9799** | click or scan EU-EC-10010181479 | | 2021-09-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Plasmacytoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9800** | click or scan EU-EC-10010181467 | | 2021-09-30 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9801** | click or scan EU-EC-10010181461 | | 2021-09-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac valve vegetation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary fibrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9802** | click or scan EU-EC-10010181367 | | 2021-09-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Lacunar infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9803** | click or scan EU-EC-10010181361 | | 2021-09-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9804** | click or scan EU-EC-10010181261 | | 2021-09-30 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9805** | click or scan EU-EC-10010181139 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9806** | click or scan EU-EC-10010180048 | | 2021-09-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **9807** | click or scan EU-EC-10010180018 | | 2021-09-30 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Cutaneous]) |
| **9808** | click or scan EU-EC-10010179943 | | 2021-09-30 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **9809** | click or scan EU-EC-10010179656 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalitis autoimmune (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Postictal state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9810 | click or scan EU-EC-10010179221 | | 2021-09-30 | Healthcare Professional | EEA | 65-85 Years | Male | Body temperature increased (1d - Recovered/Resolved - ), Fatigue (1d - Recovering/Resolving - ), Gait disturbance (1d - Recovered/Resolved - ), Somnolence (1d - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [HALOPERIDOL] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9811 | click or scan EU-EC-10010179117 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Abdominal pain (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Anal incontinence (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal injury (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Refusal of treatment by patient (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination complication (33d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9812 | click or scan EU-EC-10010179014 | | 2021-09-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Contusion (44d - Fatal - **Results in Death**, Other Medically Important Condition), Movement disorder (12d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9813 | click or scan EU-EC-10010178938 | | 2021-09-30 | Healthcare Professional | Non EEA | Not Specified | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9814 | click or scan EU-EC-10010178669 | | 2021-09-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9815 | click or scan EU-EC-10010178614 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeding intolerance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9816 | click or scan EU-EC-10010177798 | | 2021-09-30 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9817 | click or scan EU-EC-10010177519 | | 2021-09-30 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (5d - Fatal - **Results in Death**), Myalgia (5d - Fatal - **Results in Death**), Nausea (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9818 | click or scan EU-EC-10010176649 | | 2021-09-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (23d - Fatal - **Results in Death**, Other Medically Important Condition), Ageusia (n/a - Unknown - ), COVID-19 (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (23d - Fatal - **Results in Death**, Other Medically Important Condition), Gastroenteritis viral (23d - Fatal - **Results in Death**), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Vaccination failure (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9819 | click or scan EU-EC-10010176555 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9820 | click or scan EU-EC-10010176409 | | 2021-09-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Malaise (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9821 | click or scan EU-EC-10010176395 | | 2021-09-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9822 | click or scan EU-EC-10010175952 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9823 | click or scan EU-EC-10010175777 | | 2021-09-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arterial thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Embolism arterial (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) - SUSPENSION FOR INJECTION (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 9824 | click or scan EU-EC-10010175529 | | 2021-09-30 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Hemiplegia (4d - Fatal - **Results in Death**), Ischaemic stroke (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9825 | click or scan EU-EC-10010175327 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9826 | click or scan EU-EC-10010175062 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9827 | click or scan EU-EC-10010174998 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9828 | click or scan EU-EC-10010174995 | | 2021-09-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (10d - Unknown - ), Headache (10d - Unknown - ), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Unknown - ), Polymerase chain reaction positive (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (10d - Unknown - ) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9829 | click or scan EU-EC-10010174642 | | 2021-09-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**), Pruritus (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9830** | click or scan EU-EC-10010174442 | | 2021-09-30 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | OPDIVO [NIVOLUMAB] (S - Lung adenocarcinoma - Not applicable - [n/a - 240mg - Intravenous (not otherwise specified)]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9831** | click or scan EU-EC-10010173712 | | 2021-09-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - Intramuscular]) |
| **9832** | click or scan EU-EC-10010172952 | | 2021-09-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Agitation (35d - Fatal - **Results in Death**), Confusional state (35d - Fatal - **Results in Death**), Nervous system disorder (35d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Oral]) |
| **9833** | click or scan EU-EC-10010172894 | | 2021-09-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bradycardia (5d - Fatal - **Results in Death**), Confusional state (5d - Fatal - **Results in Death**), Melaena (5d - Fatal - **Results in Death**), Renal failure (5d - Fatal - **Results in Death**), Swelling face (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **9834** | click or scan EU-EC-10010171768 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9835** | click or scan EU-EC-10010171313 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Malnutrition (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9836 | click or scan EU-EC-10010170909 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Angiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central pain syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebellar stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral mass effect (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram neck (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electroencephalogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heparin-induced thrombocytopenia test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), NIH stroke scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paranasal sinus discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Perfusion brain scan (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Posterior fossa syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure like phenomena (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Status epilepticus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thalamic infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tinnitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9837 | click or scan EU-EC-10010170846 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9838 | click or scan EU-EC-10010170770 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Autopsy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 9839 | click or scan EU-EC-10010169940 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9840 | click or scan EU-EC-10010169869 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9841 | click or scan EU-EC-10010169444 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Myoclonus (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9842 | click or scan EU-EC-10010169434 | | 2021-09-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9843 | click or scan EU-EC-10010169341 | | 2021-09-29 | Healthcare Professional | EEA | 18-64 Years | Male | Mechanical ventilation (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9844 | click or scan EU-EC-10010168877 | | 2021-09-29 | Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Illness (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9845 | click or scan EU-EC-10010168842 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 9846 | click or scan EU-EC-10010168834 | | 2021-09-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9847 | click or scan EU-EC-10010168775 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9848 | click or scan EU-EC-10010168594 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9849 | click or scan EU-EC-10010168586 | | 2021-09-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9850 | click or scan EU-EC-10010168439 | | 2021-09-29 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 9851 | click or scan EU-EC-10010168438 | | 2021-09-29 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]) |
| 9852 | click or scan EU-EC-10010168413 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9853 | click or scan EU-EC-10010168401 | | 2021-09-29 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9854 | click or scan EU-EC-10010168397 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9855 | click or scan EU-EC-10010168394 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9856 | click or scan EU-EC-10010168258 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**), Supraventricular tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9857 | click or scan EU-EC-10010168190 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 9858 | click or scan EU-EC-10010168103 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Catheter site haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Device related infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal bacteraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9859 | click or scan EU-EC-10010167783 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interstitial lung disease (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Organising pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9860 | click or scan EU-EC-10010167501 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9861 | click or scan EU-EC-10010166898 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9862** | click or scan EU-EC-10010166577 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9863** | click or scan EU-EC-10010166368 | | 2021-09-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Headache (43d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **9864** | click or scan EU-EC-10010166146 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9865** | click or scan EU-EC-10010165375 | | 2021-09-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immobile (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9866** | click or scan EU-EC-10010165348 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **9867** | click or scan EU-EC-10010165301 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9868** | click or scan EU-EC-10010165206 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic kidney disease (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9869** | click or scan EU-EC-10010165076 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9870** | click or scan EU-EC-10010165074 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9871** | click or scan EU-EC-10010164890 | | 2021-09-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9872** | click or scan EU-EC-10010164683 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (14d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9873** | click or scan EU-EC-10010164668 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9874** | click or scan EU-EC-10010164332 | | 2021-09-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9875** | click or scan EU-EC-10010164103 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3mL - Intramuscular]) |
| **9876** | click or scan EU-EC-10010164092 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **9877** | click or scan EU-EC-10010163874 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9878** | click or scan EU-EC-10010163390 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fall (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Head injury (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial mass (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metastases to meninges (39d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9879** | click or scan EU-EC-10010163200 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9880** | click or scan EU-EC-10010162957 | | 2021-09-29 | Healthcare Professional | EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Arteriosclerosis (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardiac steatosis (n/a - Fatal - **Results in Death**), Cholelithiasis (n/a - Fatal - **Results in Death**), Haemorrhagic infarction (n/a - Fatal - **Results in Death**), Hepatic steatosis (n/a - Fatal - **Results in Death**), Invasive ductal breast carcinoma (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **9881** | click or scan EU-EC-10010162505 | | 2021-09-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9882** | click or scan EU-EC-10010162503 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9883** | click or scan EU-EC-10010162498 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Benign prostatic hyperplasia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetes mellitus (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9884** | click or scan EU-EC-10010162461 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Congestive cardiomyopathy (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9885** | click or scan EU-EC-10010162431 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**), Angina pectoris (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **9886** | click or scan EU-EC-10010162428 | | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **9887** | click or scan EU-EC-10010162327 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Injection site pruritus (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9888** | click or scan EU-EC-10010162302 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9889** | click or scan EU-EC-10010162299 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9890** | click or scan EU-EC-10010162167 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (144d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9891** | click or scan EU-EC-10010162130 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **9892** | click or scan EU-EC-10010162124 |  | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory syncytial virus infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9893** | click or scan EU-EC-10010162110 |  | 2021-09-29 | Healthcare Professional | EEA | 18-64 Years | Male | Acne (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Altered state of consciousness (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Decompressive craniectomy (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Slow speech (n/a - Fatal - **Results in Death**), Venous pressure increased (n/a - Fatal - **Results in Death**), Visual field defect (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9894** | click or scan EU-EC-10010162062 |  | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9895** | click or scan EU-EC-10010161992 |  | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (8d - Fatal - **Results in Death**), Feeling abnormal (8d - Fatal - **Results in Death**), Gait inability (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9896** | click or scan EU-EC-10010161853 |  | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9897** | click or scan EU-EC-10010161839 |  | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9898** | click or scan EU-EC-10010161807 |  | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Heparin-induced thrombocytopenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **9899** | click or scan EU-EC-10010161625 |  | 2021-09-29 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **9900** | click or scan EU-EC-10010161615 |  | 2021-09-29 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Cardiogenic shock (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9901 | click or scan EU-EC-10010161523 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acidosis (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**), Dyspnoea (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia staphylococcal (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumothorax (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular tachycardia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 9902 | click or scan EU-EC-10010161332 | | 2021-09-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Amnesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Balance disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epilepsy (78d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (62d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary incontinence (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9903 | click or scan EU-EC-10010161297 | | 2021-09-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (72d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysgeusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (72d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (72d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (72d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9904 | click or scan EU-EC-10010161110 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (3d - Recovered/Resolved - ), Pneumonia aspiration (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 9905 | click or scan EU-EC-10010161019 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9906 | click or scan EU-EC-10010160923 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - ), Pneumonia (8d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 9907 | click or scan EU-EC-10010160728 | | 2021-09-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9908** | click or scan EU-EC-10010160711 | | 2021-09-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **9909** | click or scan EU-EC-10010160338 | | 2021-09-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **9910** | click or scan EU-EC-10010160260 | | 2021-09-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9911** | click or scan EU-EC-10010159247 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dyspnoea (1d - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Toothache (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |
| **9912** | click or scan EU-EC-10010158675 | | 2021-09-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9913** | click or scan EU-EC-10010158466 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9914** | click or scan EU-EC-10010158105 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Recovered/Resolved - ), Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Herpes zoster (n/a - Recovered/Resolved - ), Thoracic haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9915 | click or scan EU-EC-10010157872 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram thorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive expiratory pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9916 | click or scan EU-EC-10010157420 | | 2021-09-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 9917 | click or scan EU-EC-10010157335 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9918 | click or scan EU-EC-10010157279 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoosmolar state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 9919 | click or scan EU-EC-10010157195 | | 2021-09-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9920 | click or scan EU-EC-10010157189 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Embolism arterial (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) |
| 9921 | click or scan EU-EC-10010157120 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hepatic function abnormal (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9922 | click or scan EU-EC-10010156896 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Altered state of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 9923 | click or scan EU-EC-10010156714 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9924 | click or scan EU-EC-10010156672 | | 2021-09-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Coma (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9925 | click or scan EU-EC-10010156648 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Dyspnoea (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9926 | click or scan EU-EC-10010156543 | | 2021-09-28 | Healthcare Professional | Non EEA | Not Specified | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9927 | click or scan EU-EC-10010156403 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9928 | click or scan EU-EC-10010156299 | | 2021-09-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Internal haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9929 | click or scan EU-EC-10010156200 | | 2021-09-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9930 | click or scan EU-EC-10010155531 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Angiopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9931 | click or scan EU-EC-10010155415 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9932** | click or scan EU-EC-10010154399 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9933** | click or scan EU-EC-10010154297 | | 2021-09-28 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **9934** | click or scan EU-EC-10010154282 | | 2021-09-28 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 0{DF} - Intramuscular]) |
| **9935** | click or scan EU-EC-10010154278 | | 2021-09-28 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| **9936** | click or scan EU-EC-10010154192 | | 2021-09-28 | Healthcare Professional | EEA | 18-64 Years | Male | Myalgia (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **9937** | click or scan EU-EC-10010153517 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **9938** | click or scan EU-EC-10010153179 | | 2021-09-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arterial thrombosis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Hyperhidrosis (n/a - Recovering/Resolving - ), Limb amputation (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Recovering/Resolving - ), Respiration abnormal (10min - Recovered/Resolved - ), Sepsis (n/a - Fatal - **Results in Death**), Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **9939** | click or scan EU-EC-10010152862 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **9940** | click or scan EU-EC-10010152693 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **9941** | click or scan EU-EC-10010152450 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9942** | click or scan EU-EC-10010152418 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9943 | click or scan EU-EC-10010152294 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Catheter site infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urosepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9944 | click or scan EU-EC-10010152068 | | 2021-09-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Language disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9945 | click or scan EU-EC-10010151621 | | 2021-09-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Cardiovascular disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Decubitus ulcer (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypochloraemia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypokalaemia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoosmolar state (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic alkalosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ), Pneumonia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Skin abrasion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subcutaneous haematoma (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertigo (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9946 | click or scan EU-EC-10010151109 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9947 | click or scan EU-EC-10010149696 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Road traffic accident (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 9948 | click or scan EU-EC-10010149513 | | 2021-09-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Guillain-Barre syndrome (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9949 | click or scan EU-EC-10010148755 | | 2021-09-28 | Healthcare Professional | Non EEA | Not Specified | Female | Intracranial aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9950 | click or scan EU-EC-10010148425 | | 2021-09-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 9951 | click or scan EU-EC-10010148192 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Psychiatric symptom (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9952 | click or scan EU-EC-10010148188 | | 2021-09-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 9953 | click or scan EU-EC-10010148180 | | 2021-09-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 9954 | click or scan EU-EC-10010147792 | | 2021-09-28 | Healthcare Professional | EEA | 18-64 Years | Female | Anti-platelet antibody (n/a - Unknown - ), Blood fibrinogen decreased (n/a - Unknown - Life Threatening), Brain death (n/a - Fatal - **Results in Death**, Life Threatening), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening), C-reactive protein increased (n/a - Unknown - Life Threatening), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cerebral ischaemia (n/a - Unknown - Life Threatening), Coagulopathy (n/a - Unknown - Life Threatening), Coma (n/a - Unknown - Life Threatening), Ecchymosis (n/a - Unknown - Life Threatening), Fibrin D dimer increased (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening), Heparin-induced thrombocytopenia test positive (n/a - Unknown - Life Threatening), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Migraine (n/a - Unknown - Life Threatening), Nervous system disorder (n/a - Unknown - Life Threatening), Pupils unequal (n/a - Unknown - Life Threatening), Sedation (n/a - Unknown - Life Threatening), Thrombocytopenia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9955 | click or scan EU-EC-10010145980 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Glucose urine present (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9956 | click or scan EU-EC-10010145904 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 9957 | click or scan EU-EC-10010145779 | | 2021-09-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9958** | click or scan EU-EC-10010145701 |  | 2021-09-27 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **9959** | click or scan EU-EC-10010145612 |  | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Autopsy (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **9960** | click or scan EU-EC-10010145593 |  | 2021-09-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9961** | click or scan EU-EC-10010145544 |  | 2021-09-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9962** | click or scan EU-EC-10010145502 |  | 2021-09-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9963** | click or scan EU-EC-10010145200 |  | 2021-09-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **9964** | click or scan EU-EC-10010145177 |  | 2021-09-27 | Healthcare Professional | EEA | More than 85 Years | Female | Breath sounds abnormal (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| **9965** | click or scan EU-EC-10010144943 |  | 2021-09-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| **9966** | click or scan EU-EC-10010144616 |  | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9967** | click or scan EU-EC-10010144542 |  | 2021-09-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **9968** | click or scan EU-EC-10010144264 |  | 2021-09-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Illness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 9969 | click or scan EU-EC-10010144143 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 9970 | click or scan EU-EC-10010144139 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9971 | click or scan EU-EC-10010144023 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral microhaemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hydrocephalus (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subdural haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Visual impairment (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 9972 | click or scan EU-EC-10010144012 | | 2021-09-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 9973 | click or scan EU-EC-10010143986 | | 2021-09-27 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Groin pain (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pulse abnormal (n/a - Fatal - **Results in Death**), Seizure like phenomena (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 9974 | click or scan EU-EC-10010143611 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysarthria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haematuria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hepatic cirrhosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypersomnia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia oral (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mental fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 9975 | click or scan EU-EC-10010143314 | | 2021-09-27 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9976** | click or scan EU-EC-10010143211 | | 2021-09-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **9977** | click or scan EU-EC-10010143203 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **9978** | click or scan EU-EC-10010143198 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (11d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **9979** | click or scan EU-EC-10010143009 | | 2021-09-27 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal hypokinesia (12d - Fatal - **Results in Death**, Other Medically Important Condition), Stillbirth (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **9980** | click or scan EU-EC-10010142953 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **9981** | click or scan EU-EC-10010142941 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Swelling (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **9982** | click or scan EU-EC-10010142873 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atypical pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9983** | click or scan EU-EC-10010142484 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - ), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **9984** | click or scan EU-EC-10010142393 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **9985** | click or scan EU-EC-10010142206 | | 2021-09-27 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 9986 | click or scan EU-EC-10010142135 | | 2021-09-27 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 9987 | click or scan EU-EC-10010142106 | | 2021-09-27 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9988 | click or scan EU-EC-10010142079 | | 2021-09-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 9989 | click or scan EU-EC-10010141934 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary fibrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9990 | click or scan EU-EC-10010141786 | | 2021-09-27 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 9991 | click or scan EU-EC-10010141605 | | 2021-09-27 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 9992 | click or scan EU-EC-10010141332 | | 2021-09-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Unknown - Life Threatening, Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (5h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Speech disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 9993 | click or scan EU-EC-10010141217 | | 2021-09-27 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9994 | click or scan EU-EC-10010141173 | | 2021-09-27 | Healthcare Professional | EEA | 65-85 Years | Male | Ascites (n/a - Fatal - **Results in Death**, Life Threatening), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 9995 | click or scan EU-EC-10010141151 | | 2021-09-27 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **9996** | click or scan EU-EC-10010140487 | | 2021-09-27 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **9997** | click or scan EU-EC-10010140449 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **9998** | click or scan EU-EC-10010140445 | | 2021-09-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **9999** | click or scan EU-EC-10010140282 | | 2021-09-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypoaesthesia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **10000** | click or scan EU-EC-10010140281 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **10001** | click or scan EU-EC-10010140237 | | 2021-09-27 | Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myocardial infarction (93d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10002** | click or scan EU-EC-10010140156 | | 2021-09-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| **10003** | click or scan EU-EC-10010139969 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10004** | click or scan EU-EC-10010139882 | | 2021-09-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10005** | click or scan EU-EC-10010139460 | | 2021-09-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **10006** | click or scan EU-EC-10010139400 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10007** | click or scan EU-EC-10010139392 | | 2021-09-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**), Somnolence (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **10008** | click or scan EU-EC-10010139353 | | 2021-09-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10009** | click or scan EU-EC-10010139338 | | 2021-09-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10010** | click or scan EU-EC-10010138588 | | 2021-09-27 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (5d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10011** | click or scan EU-EC-10010138241 | | 2021-09-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10012** | click or scan EU-EC-10010137976 | | 2021-09-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10013** | click or scan EU-EC-10010137938 | | 2021-09-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10014** | click or scan EU-EC-10010137704 | | 2021-09-27 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Confusional state (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Disorganised speech (n/a - Unknown - Other Medically Important Condition), Disorientation (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypersomnia (n/a - Unknown - Other Medically Important Condition), Platelet count increased (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Recovered/Resolved - Other Medically Important Condition), Sleep disorder (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10015** | click or scan EU-EC-10010137514 | | 2021-09-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10016 | click or scan EU-EC-10010136889 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Subarachnoid haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 10017 | click or scan EU-EC-10010136603 | | 2021-09-27 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure decreased (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Restlessness (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation, Immunisation - Not applicable - [1440min - .3mL - Intramuscular]) |
| 10018 | click or scan EU-EC-10010136345 | | 2021-09-27 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular fibrillation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 10019 | click or scan EU-EC-10010135831 | | 2021-09-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10020 | click or scan EU-EC-10010134707 | | 2021-09-26 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 10021 | click or scan EU-EC-10010133917 | | 2021-09-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10022 | click or scan EU-EC-10010133010 | | 2021-09-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Influenza like illness (15min - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 10023 | click or scan EU-EC-10010132363 | | 2021-09-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Traumatic lung injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site joint swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10024** | click or scan EU-EC-10010130557 | | 2021-09-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **10025** | click or scan EU-EC-10010130427 | | 2021-09-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hypoxia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10026** | click or scan EU-EC-10010130116 | | 2021-09-24 | Healthcare Professional | EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10027** | click or scan EU-EC-10010129511 | | 2021-09-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10028** | click or scan EU-EC-10010128407 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Unknown - Disabling, Other Medically Important Condition), Dehydration (n/a - Unknown - Disabling, Other Medically Important Condition), Immobile (n/a - Unknown - Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10029** | click or scan EU-EC-10010128142 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10030** | click or scan EU-EC-10010128095 | | 2021-09-24 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10031** | click or scan EU-EC-10010127602 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10032** | click or scan EU-EC-10010127497 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10033** | click or scan EU-EC-10010127446 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10034** | click or scan EU-EC-10010127438 | | 2021-09-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Diffuse large B-cell lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10035 | click or scan EU-EC-10010127332 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 10036 | click or scan EU-EC-10010127113 | | 2021-09-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10037 | click or scan EU-EC-10010127084 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10038 | click or scan EU-EC-10010126846 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 10039 | click or scan EU-EC-10010126807 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Nausea (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10040 | click or scan EU-EC-10010126356 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypercapnic coma (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 10041 | click or scan EU-EC-10010126316 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 10042 | click or scan EU-EC-10010126238 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 10043 | click or scan EU-EC-10010126201 | | 2021-09-24 | Healthcare Professional | EEA | More than 85 Years | Male | Giant cell arteritis (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Normocytic anaemia (n/a - Fatal - **Results in Death**), Purpura (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 10044 | click or scan EU-EC-10010126183 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10045** | click or scan EU-EC-10010126149 | | 2021-09-24 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10046** | click or scan EU-EC-10010126144 | | 2021-09-24 | Healthcare Professional | EEA | More than 85 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [29d - 2{DF} - Intramuscular]) |
| **10047** | click or scan EU-EC-10010126142 | | 2021-09-24 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10048** | click or scan EU-EC-10010126141 | | 2021-09-24 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10049** | click or scan EU-EC-10010125324 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10050** | click or scan EU-EC-10010125320 | | 2021-09-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10051** | click or scan EU-EC-10010125048 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10052** | click or scan EU-EC-10010124853 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cardiac ventricular thrombosis (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dilatation ventricular (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10053** | click or scan EU-EC-10010124707 | | 2021-09-24 | Healthcare Professional | EEA | 18-64 Years | Male | Cough (24d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (24d - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (24d - Fatal - **Results in Death**, Life Threatening), Somnolence (24d - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10054** | click or scan EU-EC-10010124351 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **10055** | click or scan EU-EC-10010124257 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10056** | click or scan EU-EC-10010124248 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Incontinence (n/a - Fatal - **Results in Death**), Malaise (3d - Recovered/Resolved - ), Myalgia (3d - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Vaccination site pain (2d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10057** | click or scan EU-EC-10010123898 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10058** | click or scan EU-EC-10010123555 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10059** | click or scan EU-EC-10010123471 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10060** | click or scan EU-EC-10010123060 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10061** | click or scan EU-EC-10010122804 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10062** | click or scan EU-EC-10010122751 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Male | Acute disseminated encephalomyelitis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Gait inability (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Urinary retention (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **10063** | click or scan EU-EC-10010122634 | | 2021-09-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**), Drug ineffective (6d - Fatal - **Results in Death**), Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10064 | click or scan EU-EC-10010122598 | | 2021-09-24 | Healthcare Professional | EEA | 18-64 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 10065 | click or scan EU-EC-10010122578 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10066 | click or scan EU-EC-10010122411 | | 2021-09-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10067 | click or scan EU-EC-10010122345 | | 2021-09-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10068 | click or scan EU-EC-10010122344 | | 2021-09-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 10069 | click or scan EU-EC-10010121867 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiomegaly (1d - Fatal - **Results in Death**), Hypertensive heart disease (1d - Fatal - **Results in Death**), Mitral valve prolapse (1d - Fatal - **Results in Death**), Myocardial fibrosis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10070 | click or scan EU-EC-10010121604 | | 2021-09-24 | Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain lower (n/a - Unknown - Other Medically Important Condition), Anaemia (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Hypokalaemia (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10071 | click or scan EU-EC-10010121299 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - Life Threatening), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10072 | click or scan EU-EC-10010121167 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Coronary artery occlusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10073 | click or scan EU-EC-10010120930 | | 2021-09-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cerebellar haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10074 | click or scan EU-EC-10010120763 | | 2021-09-24 | Healthcare Professional | EEA | More than 85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 10075 | click or scan EU-EC-10010120433 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (2d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (2d - Fatal - **Results in Death**, Other Medically Important Condition), Impaired work ability (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10076 | click or scan EU-EC-10010120385 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Cervical vertebral fracture (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Fatal - **Results in Death**), Quadriplegia (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Rib fracture (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 10077 | click or scan EU-EC-10010120205 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10078 | click or scan EU-EC-10010120193 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Groin pain (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10079 | click or scan EU-EC-10010120153 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Female | Duodenal ulcer perforation (n/a - Fatal - **Results in Death**), Gastric ulcer (n/a - Fatal - **Results in Death**), Peritonitis (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 10080 | click or scan EU-EC-10010119953 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (0d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10081 | click or scan EU-EC-10010119905 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10082 | click or scan EU-EC-10010119900 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - ), Blood pressure increased (n/a - Unknown - Other Medically Important Condition), Local reaction (n/a - Unknown - ), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10083 | click or scan EU-EC-10010119881 | | 2021-09-24 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10084** | click or scan EU-EC-10010119854 | | 2021-09-24 | Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperkalaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10085** | click or scan EU-EC-10010119752 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - ), Vaccination site pain (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10086** | click or scan EU-EC-10010119711 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**, Other Medically Important Condition), Chills (3d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), [DEXTROMETHORPHAN HYDROBROMIDE, PSEUDOEPHEDRINE HYDROCHLORIDE, PARACETAMOL] (S - Pyrexia - Drug withdrawn - [2d - 3 {DF} - Oral]) |
| **10087** | click or scan EU-EC-10010119644 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (10d - Unknown - Other Medically Important Condition), Asthenia (4d - Unknown - Other Medically Important Condition), Chills (10d - Unknown - Other Medically Important Condition), Cough (10d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (10d - Unknown - Other Medically Important Condition), Myalgia (10d - Unknown - Other Medically Important Condition), Pyrexia (10d - Unknown - Other Medically Important Condition), Pyrexia (4d - Unknown - Other Medically Important Condition), Vomiting (4d - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **10088** | click or scan EU-EC-10010119587 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mg - Intramuscular - More in ICSR]) |
| **10089** | click or scan EU-EC-10010119564 | | 2021-09-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (14d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dyspepsia (n/a - Unknown - ), Dyspnoea (14d - Fatal - **Results in Death**), Gait inability (n/a - Unknown - ), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (15d - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Orthopnoea (n/a - Unknown - ), Pericardial effusion (5d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (5d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10090** | click or scan EU-EC-10010119472 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Life Threatening), Multiple organ dysfunction syndrome (n/a - Not Recovered/Not Resolved - Life Threatening), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening), Pain (n/a - Not Recovered/Not Resolved - Life Threatening), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| **10091** | click or scan EU-EC-10010119230 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10092** | click or scan EU-EC-10010119215 | | 2021-09-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10093** | click or scan EU-EC-10010119190 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10094 | click or scan EU-EC-10010119164 | | 2021-09-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10095 | click or scan EU-EC-10010117579 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovered/Resolved - ), Myalgia (n/a - Unknown - Other Medically Important Condition), Night sweats (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Stillbirth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Uterine contractions abnormal (n/a - Unknown - Other Medically Important Condition), Vaccination complication (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10096 | click or scan EU-EC-10010117244 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Intestinal ulcer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10097 | click or scan EU-EC-10010116391 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10098 | click or scan EU-EC-10010116154 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous thrombosis (4d - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Thrombocytopenia (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 10099 | click or scan EU-EC-10010116149 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10100 | click or scan EU-EC-10010115397 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10101 | click or scan EU-EC-10010114622 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Aortic aneurysm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10102 | click or scan EU-EC-10010114546 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10103 | click or scan EU-EC-10010114435 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10104 | click or scan EU-EC-10010114304 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10105 | click or scan EU-EC-10010114294 | | 2021-09-23 | Healthcare Professional | EEA | 18-64 Years | Male | Immune thrombocytopenia (24h - Fatal - **Results in Death**), Thrombosis (24h - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10106 | click or scan EU-EC-10010114238 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10107 | click or scan EU-EC-10010114057 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematuria (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10108 | click or scan EU-EC-10010114039 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10109 | click or scan EU-EC-10010113951 | | 2021-09-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Movement disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 10110 | click or scan EU-EC-10010113903 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Discomfort (n/a - Unknown - ), Extrasystoles (n/a - Fatal - **Results in Death**), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Unknown - ), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10111 | click or scan EU-EC-10010113767 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Body temperature increased (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10112 | click or scan EU-EC-10010113653 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10113** | click or scan EU-EC-10010113415 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Application site vesicles (n/a - Unknown - ), Intracardiac thrombus (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **10114** | click or scan EU-EC-10010113314 |  | 2021-09-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| **10115** | click or scan EU-EC-10010113309 |  | 2021-09-23 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - 1 {DF} - Intramuscular]) |
| **10116** | click or scan EU-EC-10010113255 |  | 2021-09-23 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (17d - Fatal - **Results in Death**), Vaccination failure (17d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]) |
| **10117** | click or scan EU-EC-10010113238 |  | 2021-09-23 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10118** | click or scan EU-EC-10010113158 |  | 2021-09-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10119** | click or scan EU-EC-10010113152 |  | 2021-09-23 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [114d - n/a - Intramuscular]) |
| **10120** | click or scan EU-EC-10010112235 |  | 2021-09-23 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **10121** | click or scan EU-EC-10010112223 |  | 2021-09-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10122** | click or scan EU-EC-10010111830 |  | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10123** | click or scan EU-EC-10010111677 |  | 2021-09-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (119d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Internal haemorrhage (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphadenitis (175d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (56d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10124 | click or scan EU-EC-10010111451 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10125 | click or scan EU-EC-10010111426 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Recovering/Resolving - **Results in Death**, Other Medically Important Condition), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Mitral valve incompetence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10126 | click or scan EU-EC-10010111315 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Recovered/Resolved - ), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 10127 | click or scan EU-EC-10010111045 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10128 | click or scan EU-EC-10010110980 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10129 | click or scan EU-EC-10010110963 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acidosis (n/a - Unknown - ), Blood chloride increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood loss anaemia (n/a - Unknown - Other Medically Important Condition), Blood potassium increased (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Faeces discoloured (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Haematemesis (n/a - Unknown - Other Medically Important Condition), Hyperlactacidaemia (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ), Upper gastrointestinal haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10130 | click or scan EU-EC-10010110929 | | 2021-09-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10131 | click or scan EU-EC-10010110834 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrioventricular block (n/a - Fatal - **Results in Death**), Coronary artery occlusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Dry mouth (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Thirst (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10132 | click or scan EU-EC-10010110665 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10133 | click or scan EU-EC-10010109971 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10134 | click or scan EU-EC-10010109964 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Septic shock (1d - Fatal - **Results in Death**, Other Medically Important Condition), Subdural haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10135 | click or scan EU-EC-10010109299 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10136 | click or scan EU-EC-10010109236 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10137 | click or scan EU-EC-10010109235 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Epistaxis (14d - Unknown - Other Medically Important Condition), Induration (14d - Unknown - Other Medically Important Condition), Mobility decreased (14d - Unknown - Other Medically Important Condition), Nausea (14d - Unknown - Other Medically Important Condition), Pain (14d - Unknown - Other Medically Important Condition), Pallor (14d - Unknown - Other Medically Important Condition), Peripheral coldness (14d - Unknown - Other Medically Important Condition), Skin discolouration (14d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10138 | click or scan EU-EC-10010109115 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10139 | click or scan EU-EC-10010109077 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysarthria (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10140 | click or scan EU-EC-10010109076 | | 2021-09-23 | Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10141 | click or scan EU-EC-10010108973 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10142 | click or scan EU-EC-10010108790 | | 2021-09-23 | Healthcare Professional | EEA | 65-85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 10143 | click or scan EU-EC-10010108783 | | 2021-09-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10144 | click or scan EU-EC-10010108518 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Shock haemorrhagic (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10145 | click or scan EU-EC-10010108065 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10146 | click or scan EU-EC-10010108041 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urine output decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10147 | click or scan EU-EC-10010108035 | | 2021-09-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10148 | click or scan EU-EC-10010108025 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral vascular occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ventricular rupture (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 10149 | click or scan EU-EC-10010107992 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10150 | click or scan EU-EC-10010107987 | | 2021-09-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10151 | click or scan EU-EC-10010107876 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anal incontinence (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (27d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (27d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**), Pallor (1d - Fatal - **Results in Death**), Palpitations (27d - Fatal - **Results in Death**), Wheezing (27d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |
| 10152 | click or scan EU-EC-10010107858 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10153 | click or scan EU-EC-10010107807 | | 2021-09-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (20d - Fatal - **Results in Death**), Cough (13d - Fatal - **Results in Death**), Decreased appetite (1mo - Fatal - **Results in Death**), Drug ineffective (20d - Fatal - **Results in Death**), General physical health deterioration (1mo - Fatal - **Results in Death**), Hypogeusia (13d - Fatal - **Results in Death**), Hyposmia (13d - Fatal - **Results in Death**), Oxygen saturation decreased (13d - Fatal - **Results in Death**), Palliative care (8d - Fatal - **Results in Death**), Pyrexia (13d - Fatal - **Results in Death**), Vaccination failure (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10154 | click or scan EU-EC-10010107788 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10155 | click or scan EU-EC-10010107657 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal distension (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Abdominal pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Bacterial abdominal infection (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebellar stroke (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fluid retention (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Intracardiac thrombus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10156 | click or scan EU-EC-10010107153 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (5d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (5d - Unknown - Other Medically Important Condition), Pyrexia (5d - Unknown - Other Medically Important Condition), Trance (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10157 | click or scan EU-EC-10010106944 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiogenic shock (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Injection site swelling (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Poor quality sleep (n/a - Unknown - Other Medically Important Condition), Skin discolouration (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10158 | click or scan EU-EC-10010106492 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10159 | click or scan EU-EC-10010106224 | | 2021-09-23 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10160 | click or scan EU-EC-10010105972 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10161 | click or scan EU-EC-10010105901 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Insomnia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular - More in ICSR]) |
| 10162 | click or scan EU-EC-10010105592 | | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cyanosis (n/a - Unknown - Life Threatening), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10163** | click or scan EU-EC-10010105523 |  | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gait disturbance (n/a - Unknown - ), Ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - ), Wheezing (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **10164** | click or scan EU-EC-10010105317 |  | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (30d - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10165** | click or scan EU-EC-10010105247 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Cardiac valve disease (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10166** | click or scan EU-EC-10010105236 |  | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10167** | click or scan EU-EC-10010105214 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10168** | click or scan EU-EC-10010105185 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10169** | click or scan EU-EC-10010105161 |  | 2021-09-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10170** | click or scan EU-EC-10010105080 |  | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial necrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10171** | click or scan EU-EC-10010105034 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10172 | click or scan EU-EC-10010105010 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac dysfunction (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Productive cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10173 | click or scan EU-EC-10010104968 | | 2021-09-23 | Healthcare Professional | Non EEA | Not Specified | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10174 | click or scan EU-EC-10010104915 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (50d - Fatal - **Results in Death**), Malnutrition (50d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (50d - Fatal - **Results in Death**), Pain in extremity (50d - Fatal - **Results in Death**), Pneumonia (50d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vision blurred (50d - Fatal - **Results in Death**), Vomiting (48d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 10175 | click or scan EU-EC-10010104890 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10176 | click or scan EU-EC-10010104837 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (37d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (37d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypopnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10177 | click or scan EU-EC-10010104836 | | 2021-09-23 | Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10178 | click or scan EU-EC-10010104835 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10179 | click or scan EU-EC-10010104762 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Bone pain (n/a - Unknown - ), Brain stem haemorrhage (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - ), Pain (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10180 | click or scan EU-EC-10010104740 | | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Mood altered (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Vaccination site pain (4d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10181** | click or scan EU-EC-10010104715 |  | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute hepatitis B (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bandaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Biliary tract disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Biliary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cellulitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decubitus ulcer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10182** | click or scan EU-EC-10010104674 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10183** | click or scan EU-EC-10010104615 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthma (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **10184** | click or scan EU-EC-10010104568 |  | 2021-09-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10185** | click or scan EU-EC-10010104526 |  | 2021-09-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10186** | click or scan EU-EC-10010104457 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Bacteraemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**), Hepatic cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Jaundice cholestatic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10187** | click or scan EU-EC-10010104194 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Near death experience (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10188** | click or scan EU-EC-10010104051 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10189** | click or scan EU-EC-10010103999 |  | 2021-09-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10190** | click or scan EU-EC-10010103996 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Insomnia (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10191** | click or scan EU-EC-10010103984 | | 2021-09-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10192** | click or scan EU-EC-10010103130 | | 2021-09-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lung cancer metastatic (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **10193** | click or scan EU-EC-10010103006 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10194** | click or scan EU-EC-10010102786 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10195** | click or scan EU-EC-10010102745 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10196** | click or scan EU-EC-10010102597 | | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovering/Resolving - ), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10197** | click or scan EU-EC-10010102546 | | 2021-09-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Atypical pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10198** | click or scan EU-EC-10010102519 | | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10199** | click or scan EU-EC-10010102211 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Headache (n/a - Unknown - Life Threatening), Nausea (n/a - Unknown - Life Threatening), Thrombocytopenia (n/a - Unknown - Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10200** | click or scan EU-EC-10010101554 | | 2021-09-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10201** | click or scan EU-EC-10010101368 | | 2021-09-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anxiety (n/a - Not Recovered/Not Resolved - ), Completed suicide (n/a - Fatal - **Results in Death**), Insomnia (n/a - Not Recovered/Not Resolved - ), Psychotic disorder (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **10202** | click or scan EU-EC-10010101221 | | 2021-09-22 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **10203** | click or scan EU-EC-10010100787 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dehydration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10204** | click or scan EU-EC-10010100342 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cholelithiasis (1d - Unknown - Other Medically Important Condition), Diverticulum (1d - Unknown - Other Medically Important Condition), Pleural effusion (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ulcer haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Umbilical hernia (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10205** | click or scan EU-EC-10010099689 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Abdominal tenderness (n/a - Unknown - Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10206** | click or scan EU-EC-10010099628 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral hypoperfusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10207** | click or scan EU-EC-10010099595 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10208** | click or scan EU-EC-10010099489 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10209 | click or scan EU-EC-10010099133 | | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10210 | click or scan EU-EC-10010099117 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10211 | click or scan EU-EC-10010098979 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10212 | click or scan EU-EC-10010098951 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10213 | click or scan EU-EC-10010098899 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacterial test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mycetoma mycotic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Post procedural haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcal infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subdural haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suture insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tracheostomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10214** | click or scan EU-EC-10010098847 |  | 2021-09-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10215** | click or scan EU-EC-10010098652 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10216** | click or scan EU-EC-10010098438 |  | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure congestive (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Cystitis (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10217** | click or scan EU-EC-10010098407 |  | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Condition aggravated (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dementia Alzheimer's type (1d - Fatal - **Results in Death**, Other Medically Important Condition), Extra dose administered (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10218** | click or scan EU-EC-10010098391 |  | 2021-09-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (19d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| **10219** | click or scan EU-EC-10010098282 |  | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **10220** | click or scan EU-EC-10010098202 |  | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Male | Vascular purpura (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 2 {DF} - Intramuscular]), ELIQUIS [APIXABAN] (S - Atrial fibrillation - Drug withdrawn - [65d - 5mg - Oral]) |
| **10221** | click or scan EU-EC-10010098165 |  | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10222** | click or scan EU-EC-10010098162 |  | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10223** | click or scan EU-EC-10010098148 |  | 2021-09-22 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10224** | click or scan EU-EC-10010097741 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (76d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (76d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10225** | click or scan EU-EC-10010097725 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10226** | click or scan EU-EC-10010097595 |  | 2021-09-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10227** | click or scan EU-EC-10010097564 |  | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10228** | click or scan EU-EC-10010097540 |  | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10229** | click or scan EU-EC-10010097490 |  | 2021-09-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10230** | click or scan EU-EC-10010097488 |  | 2021-09-22 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Unknown - ), Myalgia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10231** | click or scan EU-EC-10010097462 |  | 2021-09-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10232** | click or scan EU-EC-10010097451 |  | 2021-09-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Disorientation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10233 | click or scan EU-EC-10010096390 | | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 10234 | click or scan EU-EC-10010096389 | | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 10235 | click or scan EU-EC-10010096388 | | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 10236 | click or scan EU-EC-10010096387 | | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 10237 | click or scan EU-EC-10010096385 | | 2021-09-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 10238 | click or scan EU-EC-10010096362 | | 2021-09-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10239 | click or scan EU-EC-10010096361 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10240 | click or scan EU-EC-10010096265 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10241 | click or scan EU-EC-10010096143 | | 2021-09-22 | Healthcare Professional | EEA | 18-64 Years | Male | Obstructive airways disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10242 | click or scan EU-EC-10010095867 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10243** | click or scan EU-EC-10010095768 | | 2021-09-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10244** | click or scan EU-EC-10010095510 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cognitive disorder (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Gait inability (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10245** | click or scan EU-EC-10010095306 | | 2021-09-22 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10246** | click or scan EU-EC-10010095229 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infarction (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological symptom (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10247** | click or scan EU-EC-10010095188 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Accidental overdose (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gastrooesophageal reflux disease (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Interchange of vaccine products (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Lymphoma (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Victim of abuse (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10248** | click or scan EU-EC-10010095188 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Accidental overdose (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gastrooesophageal reflux disease (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Interchange of vaccine products (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Lymphoma (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Victim of abuse (95d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10249** | click or scan EU-EC-10010095182 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (2d - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (2d - Fatal - **Results in Death**, Other Medically Important Condition), Lung neoplasm malignant (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **10250** | click or scan EU-EC-10010095109 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Unknown - Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Choking (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Unknown - Other Medically Important Condition), Poor peripheral circulation (n/a - Unknown - Other Medically Important Condition), Productive cough (n/a - Unknown - Other Medically Important Condition), Skin discolouration (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10251** | click or scan EU-EC-10010094981 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10252 | click or scan EU-EC-10010094329 | | 2021-09-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Illness (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10253 | click or scan EU-EC-10010093981 | | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 10254 | click or scan EU-EC-10010093545 | | 2021-09-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - ), Petechiae (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10255 | click or scan EU-EC-10010093517 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 10256 | click or scan EU-EC-10010093512 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bedridden (27d - Fatal - **Results in Death**), Fatigue (27d - Fatal - **Results in Death**), Feeling abnormal (27d - Fatal - **Results in Death**), Gait inability (27d - Fatal - **Results in Death**), General physical health deterioration (27d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10257 | click or scan EU-EC-10010093501 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10258 | click or scan EU-EC-10010093474 | | 2021-09-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Blood glucose abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10259 | click or scan EU-EC-10010093413 | | 2021-09-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10260 | click or scan EU-EC-10010093397 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (18d - Unknown - ), Gangrene (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 10261 | click or scan EU-EC-10010093391 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Pneumonia viral (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10262 | click or scan EU-EC-10010093312 | | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10263 | click or scan EU-EC-10010093285 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Fatal - **Results in Death**), Productive cough (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10264 | click or scan EU-EC-10010093257 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10265 | click or scan EU-EC-10010093114 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (8d - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (8d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10266 | click or scan EU-EC-10010093079 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10267 | click or scan EU-EC-10010093072 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (39d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10268 | click or scan EU-EC-10010093000 | | 2021-09-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10269 | click or scan EU-EC-10010092975 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Agonal respiration (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bradycardia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular tachycardia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10270 | click or scan EU-EC-10010092900 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (17d - Fatal - **Results in Death**), Chills (17d - Fatal - **Results in Death**), Cold sweat (17d - Fatal - **Results in Death**), Decreased appetite (17d - Fatal - **Results in Death**), Dizziness (17d - Fatal - **Results in Death**), Dyspepsia (17d - Fatal - **Results in Death**), Faeces discoloured (17d - Fatal - **Results in Death**), Fall (17d - Fatal - **Results in Death**), Feeling cold (17d - Fatal - **Results in Death**), Gait inability (17d - Fatal - **Results in Death**), Influenza like illness (17d - Fatal - **Results in Death**), Lethargy (17d - Fatal - **Results in Death**), Malaise (17d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (17d - Fatal - **Results in Death**, Other Medically Important Condition), Oesophageal pain (17d - Fatal - **Results in Death**), Oral herpes (17d - Fatal - **Results in Death**), Pruritus (17d - Fatal - **Results in Death**), Pyrexia (17d - Fatal - **Results in Death**), Tremor (17d - Fatal - **Results in Death**), Upper gastrointestinal haemorrhage (17d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10271 | click or scan EU-EC-10010092803 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10272** | click or scan EU-EC-10010092724 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10273** | click or scan EU-EC-10010092642 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10274** | click or scan EU-EC-10010092583 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10275** | click or scan EU-EC-10010092576 |  | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haemorrhagic stroke (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10276** | click or scan EU-EC-10010092435 |  | 2021-09-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (2d - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Yellow skin (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **10277** | click or scan EU-EC-10010092402 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10278** | click or scan EU-EC-10010092297 |  | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Female | Tumour marker increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10279** | click or scan EU-EC-10010092294 |  | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Aortic aneurysm rupture (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10280** | click or scan EU-EC-10010092152 |  | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10281** | click or scan EU-EC-10010092016 |  | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Weight increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10282 | click or scan EU-EC-10010091987 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10283 | click or scan EU-EC-10010091984 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10284 | click or scan EU-EC-10010091877 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10285 | click or scan EU-EC-10010091844 |  | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haemorrhagic stroke (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10286 | click or scan EU-EC-10010091840 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Encephalopathy (7d - Fatal - **Results in Death**, Other Medically Important Condition), Nervous system disorder (7d - Fatal - **Results in Death**), Pyrexia (7d - Fatal - **Results in Death**), Respiratory disorder (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10287 | click or scan EU-EC-10010091822 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10288 | click or scan EU-EC-10010091816 |  | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10289 | click or scan EU-EC-10010091800 |  | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 10290 | click or scan EU-EC-10010091742 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10291 | click or scan EU-EC-10010091692 |  | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10292 | click or scan EU-EC-10010091638 |  | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10293 | click or scan EU-EC-10010091547 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (1d - Unknown - Other Medically Important Condition), Suspected COVID-19 (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10294 | click or scan EU-EC-10010091391 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sputum discoloured (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10295 | click or scan EU-EC-10010091385 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10296 | click or scan EU-EC-10010091381 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10297 | click or scan EU-EC-10010091287 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis (n/a - Unknown - Other Medically Important Condition), Cardiac failure congestive (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Congestive hepatopathy (n/a - Unknown - Other Medically Important Condition), Hepatic cirrhosis (n/a - Unknown - Other Medically Important Condition), Hypertensive heart disease (n/a - Unknown - Other Medically Important Condition), Myocardial fibrosis (n/a - Unknown - Other Medically Important Condition), Obesity (n/a - Unknown - Other Medically Important Condition), Oedema mucosal (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary hypertension (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 10298 | click or scan EU-EC-10010091285 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10299 | click or scan EU-EC-10010091281 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10300 | click or scan EU-EC-10010091201 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac pacemaker insertion (n/a - Unknown - Caused/Prolonged Hospitalisation), Catheterisation cardiac (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrostomy (n/a - Unknown - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation), Tracheostomy (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10301 | click or scan EU-EC-10010091078 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10302 | click or scan EU-EC-10010091074 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10303 | click or scan EU-EC-10010090921 | | 2021-09-22 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product contamination (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10304 | click or scan EU-EC-10010090902 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Candida infection (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia staphylococcal (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10305 | click or scan EU-EC-10010090869 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (7d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (7d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (7d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (7d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 10306 | click or scan EU-EC-10010090811 | | 2021-09-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10307 | click or scan EU-EC-10010090769 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10308 | click or scan EU-EC-10010090768 | | 2021-09-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral atrophy (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral small vessel ischaemic disease (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10309 | click or scan EU-EC-10010090354 | | 2021-09-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10310 | click or scan EU-EC-10010090116 | | 2021-09-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (66d - Fatal - **Results in Death**), Headache (66d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10311 | click or scan EU-EC-10010088627 | | 2021-09-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Angiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bile output abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram abdomen abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram neck (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Extravasation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Perforation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary system X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10312 | click or scan EU-EC-10010088570 | | 2021-09-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10313 | click or scan EU-EC-10010087179 | | 2021-09-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10314 | click or scan EU-EC-10010086973 | | 2021-09-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10315 | click or scan EU-EC-10010086565 | | 2021-09-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10316 | click or scan EU-EC-10010086268 | | 2021-09-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10317 | click or scan EU-EC-10010086078 | | 2021-09-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10318** | click or scan EU-EC-10010083674 |  | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| **10319** | click or scan EU-EC-10010083671 |  | 2021-09-21 | Healthcare Professional | EEA | 18-64 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Sickle cell anaemia with crisis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10320** | click or scan EU-EC-10010083633 |  | 2021-09-21 | Healthcare Professional | EEA | 18-64 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10321** | click or scan EU-EC-10010083575 |  | 2021-09-21 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **10322** | click or scan EU-EC-10010083568 |  | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (29d - Fatal - **Results in Death**), Vaccination failure (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [91d - 3{DF} - Intramuscular]), TRUXIMA 500 MG CONCENTRATE FOR SOLUTION FOR INFUSION [RITUXIMAB] (S - Rheumatoid arthritis - Not applicable - [n/a - 1000mg - Intramuscular]) |
| **10323** | click or scan EU-EC-10010083529 |  | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **10324** | click or scan EU-EC-10010083504 |  | 2021-09-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fall (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10325** | click or scan EU-EC-10010083501 |  | 2021-09-21 | Healthcare Professional | EEA | 18-64 Years | Male | Body temperature fluctuation (n/a - Fatal - **Results in Death**, Life Threatening), Disturbance in attention (n/a - Fatal - **Results in Death**, Life Threatening), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10326** | click or scan EU-EC-10010083444 |  | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10327** | click or scan EU-EC-10010083441 |  | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10328** | click or scan EU-EC-10010083439 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10329** | click or scan EU-EC-10010083438 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10330** | click or scan EU-EC-10010083436 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10331** | click or scan EU-EC-10010083120 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10332** | click or scan EU-EC-10010082683 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10333** | click or scan EU-EC-10010082681 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10334** | click or scan EU-EC-10010082675 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10335** | click or scan EU-EC-10010082674 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10336** | click or scan EU-EC-10010082668 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10337** | click or scan EU-EC-10010082665 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10338 | click or scan EU-EC-10010082383 | | 2021-09-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Lung neoplasm malignant (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10339 | click or scan EU-EC-10010082382 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Female | Dysphagia (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (8d - Not Recovered/Not Resolved - ), Hypophagia (8d - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (2d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10340 | click or scan EU-EC-10010081228 | | 2021-09-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10341 | click or scan EU-EC-10010081201 | | 2021-09-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neoplasm progression (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10342 | click or scan EU-EC-10010080893 | | 2021-09-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Atypical pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiotoxicity (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**), Dyspnoea (3295d - Recovered/Resolved - Other Medically Important Condition), Gangrene (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [14s - 1 {DF} - Intramuscular]) |
| 10343 | click or scan EU-EC-10010080827 | | 2021-09-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agonal respiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asymptomatic COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Recovered/Resolved - ), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematochezia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rectal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10344 | click or scan EU-EC-10010080178 | | 2021-09-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Panic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep apnoea syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10345** | click or scan EU-EC-10010080101 | | 2021-09-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Drug ineffective (n/a - Fatal - **Results in Death**), Maternal exposure timing unspecified (n/a - Unknown - ), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10346** | click or scan EU-EC-10010080088 | | 2021-09-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **10347** | click or scan EU-EC-10010079840 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (4d - Fatal - **Results in Death**), Disturbance in attention (4d - Fatal - **Results in Death**), General physical health deterioration (4d - Fatal - **Results in Death**), Restlessness (0d - Fatal - **Results in Death**), Tachypnoea (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **10348** | click or scan EU-EC-10010079838 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **10349** | click or scan EU-EC-10010079637 | | 2021-09-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10350** | click or scan EU-EC-10010078880 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac asthma (n/a - Fatal - **Results in Death**, Life Threatening), Choking (n/a - Recovered/Resolved With Sequelae - Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Recovered/Resolved With Sequelae - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **10351** | click or scan EU-EC-10010078609 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (6wk - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10352** | click or scan EU-EC-10010078592 | | 2021-09-21 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10353** | click or scan EU-EC-10010077968 | | 2021-09-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asbestosis (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10354** | click or scan EU-EC-10010077865 | | 2021-09-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Drug ineffective (n/a - Fatal - **Results in Death**), Maternal exposure timing unspecified (n/a - Unknown - ), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10355 | click or scan EU-EC-10010077541 | | 2021-09-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10356 | click or scan EU-EC-10010077368 | | 2021-09-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Pulmonary congestion (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 10357 | click or scan EU-EC-10010076980 | | 2021-09-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Drug ineffective (n/a - Fatal - **Results in Death**), Maternal exposure timing unspecified (n/a - Unknown - ), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10358 | click or scan EU-EC-10010076754 | | 2021-09-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 10359 | click or scan EU-EC-10010076461 | | 2021-09-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (13d - Fatal - **Results in Death**), Oxygen saturation decreased (13d - Fatal - **Results in Death**), SARS-CoV-2 test positive (13d - Fatal - **Results in Death**), Vaccination failure (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 10360 | click or scan EU-EC-10010075868 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10361 | click or scan EU-EC-10010075844 | | 2021-09-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2 {DF} - n/a]) |
| 10362 | click or scan EU-EC-10010074058 | | 2021-09-21 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**), Neurological symptom (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10363 | click or scan EU-EC-10010075480 | | 2021-09-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10364 | click or scan EU-EC-10010075384 | | 2021-09-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal tenderness (n/a - Unknown - ), Asthenia (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10365** | click or scan EU-EC-10010074030 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral ventricular rupture (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Dyslalia (n/a - Unknown - Other Medically Important Condition), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Thalamus haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10366** | click or scan EU-EC-10010073923 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10367** | click or scan EU-EC-10010073478 | | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**), Vaccine associated enhanced disease (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10368** | click or scan EU-EC-10010073328 | | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]) |
| **10369** | click or scan EU-EC-10010073322 | | 2021-09-20 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **10370** | click or scan EU-EC-10010073276 | | 2021-09-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Gastroenteritis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10371** | click or scan EU-EC-10010071887 | | 2021-09-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10372** | click or scan EU-EC-10010071862 | | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatitis C (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10373** | click or scan EU-EC-10010071560 | | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10374** | click or scan EU-EC-10010071559 |  | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **10375** | click or scan EU-EC-10010071526 |  | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **10376** | click or scan EU-EC-10010071431 |  | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Choking (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10377** | click or scan EU-EC-10010071288 |  | 2021-09-20 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [40d - 1 {DF} - Intramuscular]) |
| **10378** | click or scan EU-EC-10010071241 |  | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [20d - 1 {DF} - Intramuscular]) |
| **10379** | click or scan EU-EC-10010071235 |  | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Not Recovered/Not Resolved - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| **10380** | click or scan EU-EC-10010071233 |  | 2021-09-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10381** | click or scan EU-EC-10010071058 | | 2021-09-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Shock haemorrhagic (1d - Fatal - **Results in Death**) | ADENURIC [FEBUXOSTAT] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]), PRADAXA 110 MG HARD CAPSULES [DABIGATRAN ETEXILATE] (S - Product used for unknown indication - n/a - [n/a - 110mg - Oral]), SILODYX [SILODOSIN] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BETAXOLOL, BETAXOLOL HYDROCHLORIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FORMOTEROL FUMARATE, FORMOTEROL FUMARATE DIHYDRATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, AMILORIDE HYDROCHLORIDE DIHYDRATE, FUROSEMIDE, ANHYDROUS AMILORIDE HYDROCHLORIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GLICLAZIDE] (S - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]) |
| **10382** | click or scan EU-EC-10010071056 | | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .6mL - Intramuscular]) |
| **10383** | click or scan EU-EC-10010070652 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10384** | click or scan EU-EC-10010070463 | | 2021-09-20 | Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| **10385** | click or scan EU-EC-10010070450 | | 2021-09-20 | Healthcare Professional | EEA | 18-64 Years | Male | Portosplenomesenteric venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **10386** | click or scan EU-EC-10010070398 | | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10387 | click or scan EU-EC-10010070396 | | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 10388 | click or scan EU-EC-10010070388 | | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10389 | click or scan EU-EC-10010070387 | | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 10390 | click or scan EU-EC-10010070139 | | 2021-09-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10391 | click or scan EU-EC-10010069815 | | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 10392 | click or scan EU-EC-10010069414 | | 2021-09-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10393 | click or scan EU-EC-10010069122 | | 2021-09-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2 {DF} - n/a]) |
| 10394 | click or scan EU-EC-10010068999 | | 2021-09-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Unknown - ), Fatigue (2d - Unknown - ), Pyrexia (2d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 10395 | click or scan EU-EC-10010068778 | | 2021-09-20 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10396 | click or scan EU-EC-10010068351 | | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10397 | click or scan EU-EC-10010067817 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10398** | click or scan EU-EC-10010067807 | | 2021-09-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure systolic decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Colitis ischaemic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flatulence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrointestinal necrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ileus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10399** | click or scan EU-EC-10010067765 | | 2021-09-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Apnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10400** | click or scan EU-EC-10010067421 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **10401** | click or scan EU-EC-10010067370 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10402** | click or scan EU-EC-10010067182 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Incontinence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vision blurred (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10403** | click or scan EU-EC-10010067029 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10404** | click or scan EU-EC-10010066628 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Coronary artery disease (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocardial fibrosis (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10405** | click or scan EU-EC-10010066305 | | 2021-09-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10406** | click or scan EU-EC-10010065797 | | 2021-09-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Embolism (n/a - Fatal - **Results in Death**, Life Threatening), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10407** | click or scan EU-EC-10010065784 | | 2021-09-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Pain (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10408** | click or scan EU-EC-10010065753 | | 2021-09-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10409** | click or scan EU-EC-10010065575 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10410** | click or scan EU-EC-10010065496 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyslalia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - ), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory depression (n/a - Fatal - **Results in Death**), Thrombotic cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10411** | click or scan EU-EC-10010065474 | | 2021-09-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Bone cancer (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Mobility decreased (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10412** | click or scan EU-EC-10010065443 | | 2021-09-20 | Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10413** | click or scan EU-EC-10010065427 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fibrin D dimer decreased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10414** | click or scan EU-EC-10010065217 | | 2021-09-20 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10415 | click or scan EU-EC-10010065148 | | 2021-09-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Carotid artery aneurysm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Carotid artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haematoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral mass effect (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral vasoconstriction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mesenteric haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulmonary congestion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis mesenteric vessel (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| 10416 | click or scan EU-EC-10010063720 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm rupture (1 d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10417 | click or scan EU-EC-10010063056 | | 2021-09-20 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| 10418 | click or scan EU-EC-10010062232 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10419 | click or scan EU-EC-10010061310 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10420 | click or scan EU-EC-10010061196 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10421 | click or scan EU-EC-10010060820 | | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myocardial ischaemia (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10422 | click or scan EU-EC-10010060739 | | 2021-09-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vascular occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10423 | click or scan EU-EC-10010060441 |  | 2021-09-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10424 | click or scan EU-EC-10010058866 |  | 2021-09-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Amaurosis (n/a - Fatal - **Results in Death**), Aphasia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 10425 | click or scan EU-EC-10010058665 |  | 2021-09-18 | Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (12d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (12d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (12d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (12d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (9d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - 1{DF} - Intramuscular]) |
| 10426 | click or scan EU-EC-10010058574 |  | 2021-09-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10427 | click or scan EU-EC-10010057651 |  | 2021-09-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Not Recovered/Not Resolved - ), Hypotonia (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ), Renal infarct (n/a - Unknown - Other Medically Important Condition), Spleen ischaemia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10428 | click or scan EU-EC-10010057648 |  | 2021-09-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Renal infarct (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VIAGRA [SILDENAFIL, SILDENAFIL CITRATE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10429 | click or scan EU-EC-10010055609 |  | 2021-09-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Pain (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10430 | click or scan EU-EC-10010055530 |  | 2021-09-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Alanine aminotransferase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug intolerance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastroenteritis viral (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**), Influenza (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Photophobia (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10431 | click or scan EU-EC-10010051912 | | 2021-09-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 10432 | click or scan EU-EC-10010051877 | | 2021-09-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Grip strength decreased (n/a - Fatal - **Results in Death**), Venous thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 10433 | click or scan EU-EC-10010051524 | | 2021-09-18 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Cough (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mg - Intramuscular]) |
| 10434 | click or scan EU-EC-10010048074 | | 2021-09-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Guillain-Barre syndrome (127d - Fatal - **Results in Death**), Paralysis (127d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 10435 | click or scan EU-EC-10010048567 | | 2021-09-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10436 | click or scan EU-EC-10010046953 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10437 | click or scan EU-EC-10010045574 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10438 | click or scan EU-EC-10010045559 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Life Threatening), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10439 | click or scan EU-EC-10010045077 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10440 | click or scan EU-EC-10010045008 | | 2021-09-17 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10441 | click or scan EU-EC-10010044698 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hot flush (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10442 | click or scan EU-EC-10010044306 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10443 | click or scan EU-EC-10010044149 | | 2021-09-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10444 | click or scan EU-EC-10010044044 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10445 | click or scan EU-EC-10010043850 | | 2021-09-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Pancreatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10446 | click or scan EU-EC-10010042630 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10447 | click or scan EU-EC-10010042394 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10448 | click or scan EU-EC-10010042125 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10449 | click or scan EU-EC-10010041875 | | 2021-09-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Illness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10450 | click or scan EU-EC-10010041767 | | 2021-09-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10451 | click or scan EU-EC-10010041728 | | 2021-09-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Product contamination physical (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10452 | click or scan EU-EC-10010041542 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Retching (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10453 | click or scan EU-EC-10010041384 | | 2021-09-17 | Healthcare Professional | Non EEA | Not Specified | Female | Platelet count decreased (17d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10454 | click or scan EU-EC-10010041182 | | 2021-09-17 | Healthcare Professional | EEA | More than 85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Faeces discoloured (n/a - Recovered/Resolved - ), Haemorrhage urinary tract (31d - Recovered/Resolved - ), Joint swelling (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 10455 | click or scan EU-EC-10010040967 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 10456 | click or scan EU-EC-10010040964 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 10457 | click or scan EU-EC-10010040961 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 10458 | click or scan EU-EC-10010040850 | | 2021-09-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Depressed level of consciousness (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 10459 | click or scan EU-EC-10010040695 | | 2021-09-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10460 | click or scan EU-EC-10010040631 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10461 | click or scan EU-EC-10010040564 | | 2021-09-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10462** | click or scan EU-EC-10010040365 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Haematocrit decreased (n/a - Unknown - Other Medically Important Condition), Haemoglobin decreased (n/a - Unknown - Other Medically Important Condition), Lymphocyte count decreased (n/a - Unknown - Other Medically Important Condition), Mean cell haemoglobin concentration decreased (n/a - Unknown - Other Medically Important Condition), Melaena (n/a - Unknown - Caused/Prolonged Hospitalisation), Metamyelocyte count increased (n/a - Unknown - Other Medically Important Condition), Myelocyte count increased (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Red blood cell count decreased (n/a - Unknown - Other Medically Important Condition), Red cell distribution width increased (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10463** | click or scan EU-EC-10010040316 | | 2021-09-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anaemia (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gastric haemorrhage (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Portal vein thrombosis (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10464** | click or scan EU-EC-10010039469 | | 2021-09-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10465** | click or scan EU-EC-10010039242 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10466** | click or scan EU-EC-10010038838 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Metabolic function test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Microbiology test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sputum culture (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10467** | click or scan EU-EC-10010038724 | | 2021-09-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10468** | click or scan EU-EC-10010038690 | | 2021-09-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Back pain (n/a - Unknown - ), Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10469** | click or scan EU-EC-10010038606 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Incontinence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10470 | click or scan EU-EC-10010038593 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Carcinoid tumour pulmonary (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10471 | click or scan EU-EC-10010038589 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Extra dose administered (n/a - Unknown - ), Hyperhidrosis (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Unknown - ), Oropharyngeal pain (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10472 | click or scan EU-EC-10010038562 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10473 | click or scan EU-EC-10010038557 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dehydration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperglycaemic hyperosmolar nonketotic syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Severe fever with thrombocytopenia syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10474 | click or scan EU-EC-10010038547 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood glucose increased (n/a - Unknown - ), Blood triglycerides increased (n/a - Unknown - ), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Glycosylated haemoglobin increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10475 | click or scan EU-EC-10010038544 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10476 | click or scan EU-EC-10010038542 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10477 | click or scan EU-EC-10010038540 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Vaccination site pain (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10478 | click or scan EU-EC-10010038420 | | 2021-09-17 | Healthcare Professional | EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 10479 | click or scan EU-EC-10010038059 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10480 | click or scan EU-EC-10010037708 | | 2021-09-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Influenza (n/a - Not Recovered/Not Resolved - ), Vascular stent occlusion (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10481 | click or scan EU-EC-10010036993 | | 2021-09-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10482 | click or scan EU-EC-10010036141 | | 2021-09-17 | Healthcare Professional | EEA | 65-85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ballismus (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10483 | click or scan EU-EC-10010036013 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Arrhythmia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Other Medically Important Condition), Liver disorder (n/a - Unknown - ), Pupillary reflex impaired (n/a - Unknown - Other Medically Important Condition), Rhabdomyolysis (n/a - Unknown - Other Medically Important Condition), Ventricular hypokinesia (n/a - Unknown - Other Medically Important Condition), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10484 | click or scan EU-EC-10010035996 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10485 | click or scan EU-EC-10010035211 | | 2021-09-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10486 | click or scan EU-EC-10010035209 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10487 | click or scan EU-EC-10010034364 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10488 | click or scan EU-EC-10010034361 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10489 | click or scan EU-EC-10010034355 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10490 | click or scan EU-EC-10010034268 | | 2021-09-17 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 10491 | click or scan EU-EC-10010033901 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10492 | click or scan EU-EC-10010033685 | | 2021-09-17 | Healthcare Professional | EEA | 18-64 Years | Female | Administration site pain (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Arthralgia (36h - Recovering/Resolving - ), Body temperature increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Recovering/Resolving - ), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heparin-induced thrombocytopenia test positive (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypofibrinogenaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza like illness (1d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - ), Muscle spasms (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - ), Prothrombin time shortened (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tonsillitis (n/a - Recovering/Resolving - ) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10493 | click or scan EU-EC-10010033630 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Troponin T increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10494 | click or scan EU-EC-10010033620 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10495 | click or scan EU-EC-10010033310 | | 2021-09-17 | Healthcare Professional | EEA | More than 85 Years | Male | Blindness (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10496 | click or scan EU-EC-10010033309 | | 2021-09-17 | Healthcare Professional | EEA | More than 85 Years | Male | Arthralgia (n/a - Unknown - ), Dementia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 10497 | click or scan EU-EC-10010032968 | | 2021-09-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Neoplasm progression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10498 | click or scan EU-EC-10010032962 | | 2021-09-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10499 | click or scan EU-EC-10010032955 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10500 | click or scan EU-EC-10010032935 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10501 | click or scan EU-EC-10010032934 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10502 | click or scan EU-EC-10010032932 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10503 | click or scan EU-EC-10010032914 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haematemesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10504 | click or scan EU-EC-10010032331 | | 2021-09-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (6d - Fatal - **Results in Death**, Other Medically Important Condition), Altered state of consciousness (6d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 10505 | click or scan EU-EC-10010032211 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10506 | click or scan EU-EC-10010032210 | | 2021-09-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Abdominal discomfort (n/a - Unknown - ), Appendicitis (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Clostridium difficile infection (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10507 | click or scan EU-EC-10010032085 | | 2021-09-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vascular injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10508 | click or scan EU-EC-10010032075 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - ), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 10509 | click or scan EU-EC-10010032066 | | 2021-09-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10510 | click or scan EU-EC-10010031780 | | 2021-09-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10511 | click or scan EU-EC-10010030856 | | 2021-09-17 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10512 | click or scan EU-EC-10010029883 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10513 | click or scan EU-EC-10010029846 | | 2021-09-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Skin discolouration (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10514 | click or scan EU-EC-10010029829 | | 2021-09-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10515 | click or scan EU-EC-10010029657 | | 2021-09-16 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10516 | click or scan EU-EC-10010029313 | | 2021-09-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10517** | click or scan EU-EC-10010028907 | | 2021-09-16 | Healthcare Professional | EEA | 18-64 Years | Female | Blood ketone body present (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**), Head discomfort (n/a - Unknown - ), Headache (n/a - Recovered/Resolved - ), Immune-mediated adverse reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Skin discolouration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10518** | click or scan EU-EC-10010028885 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Vertebrobasilar stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10519** | click or scan EU-EC-10010028676 | | 2021-09-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10520** | click or scan EU-EC-10010028236 | | 2021-09-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Anuria (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Peripheral artery occlusion (n/a - Fatal - **Results in Death**), Skin discolouration (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10521** | click or scan EU-EC-10010027322 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10522** | click or scan EU-EC-10010026549 | | 2021-09-16 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth abnormality (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **10523** | click or scan EU-EC-10010026199 | | 2021-09-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10524** | click or scan EU-EC-10010026157 | | 2021-09-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10525** | click or scan EU-EC-10010025922 | | 2021-09-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10526** | click or scan EU-EC-10010025412 | | 2021-09-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10527** | click or scan EU-EC-10010025397 | | 2021-09-16 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10528** | click or scan EU-EC-10010025337 | | 2021-09-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cholangitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| **10529** | click or scan EU-EC-10010025306 | | 2021-09-16 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**) | MEKINIST 2.0 MG FILM-COATED TABLETS [TRAMETINIB] (S - Lung adenocarcinoma stage IV - Dose not changed - [404d - 2mg - Oral]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), TAFINLAR 50 MG HARD CAPSULES [DABRAFENIB] (S - Lung adenocarcinoma stage IV - Dose not changed - [404d - 100mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (S - Hypertension - Dose not changed - [n/a - 10mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Cardiovascular event prophylaxis - Dose not changed - [n/a - 10mg - Oral]), [D,L-LYSINE ACETYLSALICYLATE] (S - Cardiovascular event prophylaxis - Dose not changed - [n/a - 1{DF} - Oral]), [METFORMIN HYDROCHLORIDE] (S - Insulin-requiring type 2 diabetes mellitus - Dose not changed - [n/a - 850mg - Oral]), [VALSARTAN] (S - Hypertension - Dose not changed - [n/a - 160mg - Oral]) |
| **10530** | click or scan EU-EC-10010025278 | | 2021-09-16 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **10531** | click or scan EU-EC-10010025270 | | 2021-09-16 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (6d - Fatal - **Results in Death**), COVID-19 pneumonia (6d - Fatal - **Results in Death**), Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| **10532** | click or scan EU-EC-10010025263 | | 2021-09-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| **10533** | click or scan EU-EC-10010025186 | | 2021-09-16 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10534 | click or scan EU-EC-10010025127 | | 2021-09-16 | Healthcare Professional | EEA | More than 85 Years | Female | Brain stem stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 10535 | click or scan EU-EC-10010025022 | | 2021-09-16 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10536 | click or scan EU-EC-10010024812 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Unknown - Other Medically Important Condition), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Organ failure (14d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 10537 | click or scan EU-EC-10010024605 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10538 | click or scan EU-EC-10010024600 | | 2021-09-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10539 | click or scan EU-EC-10010024442 | | 2021-09-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10540 | click or scan EU-EC-10010023763 | | 2021-09-16 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10541 | click or scan EU-EC-10010023763 | | 2021-09-16 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10542 | click or scan EU-EC-10010023603 | | 2021-09-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10543 | click or scan EU-EC-10010023594 | | 2021-09-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10544** | click or scan EU-EC-10010023567 | | 2021-09-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10545** | click or scan EU-EC-10010023073 | | 2021-09-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **10546** | click or scan EU-EC-10010022287 | | 2021-09-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **10547** | click or scan EU-EC-10010022014 | | 2021-09-16 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Abortion spontaneous (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10548** | click or scan EU-EC-10010021986 | | 2021-09-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10549** | click or scan EU-EC-10010021851 | | 2021-09-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10550** | click or scan EU-EC-10010021692 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10551** | click or scan EU-EC-10010020833 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10552** | click or scan EU-EC-10010020819 | | 2021-09-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - ), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10553** | click or scan EU-EC-10010020783 | | 2021-09-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Restlessness (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10554** | click or scan EU-EC-10010020282 |  | 2021-09-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10555** | click or scan EU-EC-10010020227 |  | 2021-09-16 | Healthcare Professional | EEA | 65-85 Years | Female | Areflexia (2d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Diplegia (2d - Fatal - **Results in Death**, Other Medically Important Condition), Guillain-Barre syndrome (2d - Fatal - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Walking disability (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **10556** | click or scan EU-EC-10010020011 |  | 2021-09-16 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myositis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **10557** | click or scan EU-EC-10010018665 |  | 2021-09-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **10558** | click or scan EU-EC-10010018483 |  | 2021-09-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **10559** | click or scan EU-EC-10010017959 |  | 2021-09-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10560** | click or scan EU-EC-10010017895 |  | 2021-09-16 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10561** | click or scan EU-EC-10010017735 |  | 2021-09-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (12d - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10562** | click or scan EU-EC-10010017527 |  | 2021-09-16 | Healthcare Professional | EEA | 18-64 Years | Male | Subarachnoid haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10563 | click or scan EU-EC-10010017001 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apnoea (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pupillary reflex impaired (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (570min - Recovered/Resolved - ), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10564 | click or scan EU-EC-10010016845 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10565 | click or scan EU-EC-10010016785 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atypical pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), B-cell lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic lymphocytic leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Obesity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10566 | click or scan EU-EC-10010016598 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10567 | click or scan EU-EC-10010016525 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10568 | click or scan EU-EC-10010016502 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10569 | click or scan EU-EC-10010016482 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Amnesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood bilirubin decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood potassium increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Red blood cell count increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10570** | click or scan EU-EC-10010016041 | | 2021-09-15 | Healthcare Professional | EEA | 18-64 Years | Female | Anti-platelet antibody positive (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **10571** | click or scan EU-EC-10010015883 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10572** | click or scan EU-EC-10010015718 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| **10573** | click or scan EU-EC-10010015451 | | 2021-09-15 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10574** | click or scan EU-EC-10010015450 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10575** | click or scan EU-EC-10010015437 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Encephalitis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple fractures (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myelitis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Respiratory tract congestion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Spondylitis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10576** | click or scan EU-EC-10010015404 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10577** | click or scan EU-EC-10010015384 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Unknown - ), Blood pressure increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Eating disorder (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Heart rate decreased (n/a - Unknown - ), Hot flush (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Oedema (n/a - Unknown - Other Medically Important Condition), Red blood cell count decreased (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - ), Urinary incontinence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10578** | click or scan EU-EC-10010015383 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cardiac failure congestive (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Gait disturbance (n/a - Unknown - Life Threatening, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypotension (n/a - Unknown - Life Threatening, Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - Life Threatening, Other Medically Important Condition), Mobility decreased (n/a - Unknown - Life Threatening, Other Medically Important Condition), Walking aid user (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10579** | click or scan EU-EC-10010015315 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10580** | click or scan EU-EC-10010015247 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10581** | click or scan EU-EC-10010015123 | | 2021-09-15 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**), Premature baby (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **10582** | click or scan EU-EC-10010014758 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Choking (n/a - Unknown - Other Medically Important Condition), Communication disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal discomfort (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10583** | click or scan EU-EC-10010014580 | | 2021-09-15 | Non Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (4wk - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **10584** | click or scan EU-EC-10010014544 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10585** | click or scan EU-EC-10010014512 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatorenal syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malignant neoplasm progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metastases to liver (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10586** | click or scan EU-EC-10010014506 | | 2021-09-15 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Extra dose administered (n/a - Unknown - ), Off label use (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10587** | click or scan EU-EC-10010014479 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10588** | click or scan EU-EC-10010014399 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Autopsy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), General symptom (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Viral infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10589** | click or scan EU-EC-10010014321 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10590** | click or scan EU-EC-10010014273 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10591** | click or scan EU-EC-10010013964 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cellulitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Hallucination (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10592** | click or scan EU-EC-10010013586 | | 2021-09-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10593** | click or scan EU-EC-10010013349 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Melaena (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10594** | click or scan EU-EC-10010013153 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10595** | click or scan EU-EC-10010013027 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10596** | click or scan EU-EC-10010012838 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10597** | click or scan EU-EC-10010012700 | | 2021-09-15 | Healthcare Professional | EEA | 18-64 Years | Female | Encephalitis autoimmune (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nosocomial infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10598** | click or scan EU-EC-10010012697 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Haemoptysis (n/a - Unknown - Other Medically Important Condition), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10599** | click or scan EU-EC-10010012692 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Basilar artery occlusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Basilar artery thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heat illness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hyperthermia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Temperature regulation disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10600** | click or scan EU-EC-10010012382 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10601** | click or scan EU-EC-10010012239 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic valve stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Hypophagia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10602** | click or scan EU-EC-10010012192 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Faeces discoloured (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10603** | click or scan EU-EC-10010012083 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10604** | click or scan EU-EC-10010012079 | | 2021-09-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Unknown - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - ), Swelling face (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10605 | click or scan EU-EC-10010012075 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10606 | click or scan EU-EC-10010012069 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Contusion (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition), Skin abrasion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10607 | click or scan EU-EC-10010012050 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10608 | click or scan EU-EC-10010012016 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 10609 | click or scan EU-EC-10010011896 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 10610 | click or scan EU-EC-10010011089 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) |
| 10611 | click or scan EU-EC-10010011024 | | 2021-09-15 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (29d - Fatal - **Results in Death**), Vaccination failure (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| 10612 | click or scan EU-EC-10010011019 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 10613 | click or scan EU-EC-10010010970 | | 2021-09-15 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Hypertension (n/a - Fatal - **Results in Death**), Hypotonia (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 10614 | click or scan EU-EC-10010010887 | | 2021-09-15 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 10615 | click or scan EU-EC-10010010734 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10616** | click or scan EU-EC-10010010653 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10617** | click or scan EU-EC-10010010538 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric venous occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superior mesenteric artery syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10618** | click or scan EU-EC-10010010347 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10619** | click or scan EU-EC-10010010319 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10620** | click or scan EU-EC-10010010235 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Flank pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10621** | click or scan EU-EC-10010009745 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (126d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (126d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10622** | click or scan EU-EC-10010009509 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Organ failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10623** | click or scan EU-EC-10010009302 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Hemiparesis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Tongue movement disturbance (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10624 | click or scan EU-EC-10010009238 | | 2021-09-15 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10625 | click or scan EU-EC-10010009236 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Female | Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10626 | click or scan EU-EC-10010009233 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10627 | click or scan EU-EC-10010009220 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Subdural haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10628 | click or scan EU-EC-10010009219 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10629 | click or scan EU-EC-10010009212 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Unknown - ), Incorrect route of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous]) |
| 10630 | click or scan EU-EC-10010009208 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10631 | click or scan EU-EC-10010009203 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10632 | click or scan EU-EC-10010009202 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10633** | click or scan EU-EC-10010009196 |  | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Cerebrovascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10634** | click or scan EU-EC-10010009160 |  | 2021-09-15 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10635** | click or scan EU-EC-10010007831 |  | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10636** | click or scan EU-EC-10010007798 |  | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Unknown - Other Medically Important Condition), Brain death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Condition aggravated (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Decreased appetite (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Fatigue (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), General physical health deterioration (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypotension (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Interstitial lung disease (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myositis (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pneumonia (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Renal failure (37d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10637** | click or scan EU-EC-10010007797 |  | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10638** | click or scan EU-EC-10010007709 |  | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10639** | click or scan EU-EC-10010007633 |  | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10640** | click or scan EU-EC-10010007566 |  | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10641** | click or scan EU-EC-10010007562 |  | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10642 | click or scan EU-EC-10010007477 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10643 | click or scan EU-EC-10010007340 | | 2021-09-15 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10644 | click or scan EU-EC-10010007337 | | 2021-09-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10645 | click or scan EU-EC-10010007180 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acidosis (1d - Fatal - **Results in Death**), Acute respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Bronchostenosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diaphragmatic hernia (1d - Fatal - **Results in Death**), Drug ineffective (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Hiatus hernia (1d - Fatal - **Results in Death**), Leukocytosis (1d - Fatal - **Results in Death**), Lung consolidation (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary artery stenosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary mass (1d - Fatal - **Results in Death**), Pulmonary valve stenosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10646 | click or scan EU-EC-10010007159 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Extra dose administered (1d - Recovered/Resolved - ), Malaise (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10647 | click or scan EU-EC-10010007122 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acidosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Apathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Delirium (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperuricaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Insomnia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Restlessness (n/a - Unknown - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10648 | click or scan EU-EC-10010006964 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Intracardiac thrombus (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 10649 | click or scan EU-EC-10010006937 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10650 | click or scan EU-EC-10010006703 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10651** | click or scan EU-EC-10010006697 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cytokine storm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10652** | click or scan EU-EC-10010006683 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **10653** | click or scan EU-EC-10010006677 | | 2021-09-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10654** | click or scan EU-EC-10010006657 | | 2021-09-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pancreatitis acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10655** | click or scan EU-EC-10010006148 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10656** | click or scan EU-EC-10010006147 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (23d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10657** | click or scan EU-EC-10010006138 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Unknown - ), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **10658** | click or scan EU-EC-10010006116 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**), Cough (3d - Fatal - **Results in Death**), General physical health deterioration (2d - Fatal - **Results in Death**), Oxygen saturation decreased (2d - Fatal - **Results in Death**), Rales (3d - Fatal - **Results in Death**), Respiration abnormal (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10659** | click or scan EU-EC-10010005958 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10660** | click or scan EU-EC-10010005892 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hepatic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10661** | click or scan EU-EC-10010005711 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**), Device failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10662** | click or scan EU-EC-10010005659 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (5d - Fatal - **Results in Death**), Dyspnoea (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10663** | click or scan EU-EC-10010005606 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10664** | click or scan EU-EC-10010005579 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ovarian mass (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10665** | click or scan EU-EC-10010005475 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Congestive cardiomyopathy (19d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (19d - Unknown - ), Headache (19d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10666** | click or scan EU-EC-10010005343 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10667** | click or scan EU-EC-10010005270 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - .3mL - Other]), [EDOXABAN] (S - Atrial fibrillation - Unknown - [n/a - 30mg - Oral]) |
| **10668** | click or scan EU-EC-10010005247 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Hypoplastic left heart syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10669** | click or scan EU-EC-10010005172 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10670** | click or scan EU-EC-10010005131 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood glucose increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood uric acid increased (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10671** | click or scan EU-EC-10010005036 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10672** | click or scan EU-EC-10010005028 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10673** | click or scan EU-EC-10010005008 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10674** | click or scan EU-EC-10010005000 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Eye movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - ), Organ failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10675** | click or scan EU-EC-10010004995 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastroenteritis (n/a - Recovering/Resolving - Other Medically Important Condition), Staphylococcal bacteraemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10676** | click or scan EU-EC-10010004952 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10677** | click or scan EU-EC-10010004948 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Discomfort (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10678** | click or scan EU-EC-10010004815 | | 2021-09-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10679** | click or scan EU-EC-10010004798 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diaphragmatic disorder (2d - Fatal - **Results in Death**), Myopathy (2d - Fatal - **Results in Death**), Myositis (2d - Fatal - **Results in Death**), Pneumonia aspiration (2d - Fatal - **Results in Death**, Other Medically Important Condition), Systemic inflammatory response syndrome (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10680** | click or scan EU-EC-10010004685 | | 2021-09-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10681** | click or scan EU-EC-10010004670 | | 2021-09-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10682** | click or scan EU-EC-10010004621 | | 2021-09-15 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **10683** | click or scan EU-EC-10010004477 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10684** | click or scan EU-EC-10010004308 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10685** | click or scan EU-EC-10010004301 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10686** | click or scan EU-EC-10010004194 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (14d - Fatal - **Results in Death**, Other Medically Important Condition), Acute respiratory failure (14d - Fatal - **Results in Death**, Other Medically Important Condition), Atelectasis (14d - Fatal - **Results in Death**), COVID-19 (14d - Fatal - **Results in Death**), Cardiac failure congestive (14d - Fatal - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (14d - Fatal - **Results in Death**, Other Medically Important Condition), Hyponatraemia (14d - Fatal - **Results in Death**), Lung opacity (14d - Fatal - **Results in Death**), Pleural effusion (14d - Fatal - **Results in Death**), Pneumonia viral (14d - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (14d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10687** | click or scan EU-EC-10010004164 | | 2021-09-15 | Healthcare Professional | EEA | 18-64 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**), Cerebellar haemorrhage (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **10688** | click or scan EU-EC-10010004077 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10689** | click or scan EU-EC-10010004037 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10690** | click or scan EU-EC-10010003935 | | 2021-09-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10691** | click or scan EU-EC-10010003926 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10692** | click or scan EU-EC-10010003911 | | 2021-09-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10693** | click or scan EU-EC-10010000971 | | 2021-09-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| **10694** | click or scan EU-EC-10010002880 | | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10695** | click or scan EU-EC-10010002765 | | 2021-09-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10696** | click or scan EU-EC-10010002625 | | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dystonia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Oculogyric crisis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10697** | click or scan EU-EC-10010002623 | | 2021-09-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10698** | click or scan EU-EC-10010002221 | | 2021-09-14 | Healthcare Professional | EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Ecchymosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Embolism (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Transverse sinus thrombosis (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **10699** | click or scan EU-EC-10010002040 | | 2021-09-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Coma (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10700** | click or scan EU-EC-10010001150 | | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **10701** | click or scan EU-EC-10010000571 | | 2021-09-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10702** | click or scan EU-EC-10010000073 | | 2021-09-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10703** | click or scan EU-EC-10009999643 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10704** | click or scan EU-EC-10009999299 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10705** | click or scan EU-EC-10009998805 | | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Haematoma (n/a - Unknown - ), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10706** | click or scan EU-EC-10009998733 | | 2021-09-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Concomitant disease progression (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug interaction (n/a - Unknown - ), Fatigue (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]), [CANDESARTAN CILEXETIL] (S - n/a - Not applicable - [n/a - n/a - n/a]), [DILTIAZEM HYDROCHLORIDE] (S - n/a - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (S - n/a - Not applicable - [n/a - n/a - n/a]), [SPIRONOLACTONE] (S - n/a - Not applicable - [n/a - n/a - n/a]), [WARFARIN SODIUM] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **10707** | click or scan EU-EC-10009998693 | | 2021-09-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10708** | click or scan EU-EC-10009998682 | | 2021-09-14 | Non Healthcare Professional | EEA | Not Specified | Female | Asthenia (n/a - Unknown - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - **Results in Death**), Diarrhoea (n/a - Unknown - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Feeling cold (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10709** | click or scan EU-EC-10009998651 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10710** | click or scan EU-EC-10009998650 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10711** | click or scan EU-EC-10009997714 | | 2021-09-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10712** | click or scan EU-EC-10009997290 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10713** | click or scan EU-EC-10009996304 | | 2021-09-14 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10714** | click or scan EU-EC-10009996273 | | 2021-09-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| **10715** | click or scan EU-EC-10009996263 | | 2021-09-14 | Healthcare Professional | EEA | 18-64 Years | Female | Epilepsy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |
| **10716** | click or scan EU-EC-10009996256 | | 2021-09-14 | Healthcare Professional | EEA | More than 85 Years | Male | Acquired haemophilia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **10717** | click or scan EU-EC-10009996254 | | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **10718** | click or scan EU-EC-10009996173 | | 2021-09-14 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10719** | click or scan EU-EC-10009996162 | | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **10720** | click or scan EU-EC-10009996161 | | 2021-09-14 | Healthcare Professional | EEA | More than 85 Years | Female | Bacterial infection (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10721** | click or scan EU-EC-10009996159 | | 2021-09-14 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**), Testicular oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **10722** | click or scan EU-EC-10009996158 | | 2021-09-14 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| **10723** | click or scan EU-EC-10009996152 | | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **10724** | click or scan EU-EC-10009996135 | | 2021-09-14 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10725** | click or scan EU-EC-10009996116 | | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (23d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10726** | click or scan EU-EC-10009996042 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Bundle branch block left (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Jaundice (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic acidosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neutrophilia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10727** | click or scan EU-EC-10009995850 | | 2021-09-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10728** | click or scan EU-EC-10009995841 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10729** | click or scan EU-EC-10009995547 | | 2021-09-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10730** | click or scan EU-EC-10009995536 | | 2021-09-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cough (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Pulmonary fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10731** | click or scan EU-EC-10009995534 | | 2021-09-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10732** | click or scan EU-EC-10009995512 | | 2021-09-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10733** | click or scan EU-EC-10009995390 | | 2021-09-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10734** | click or scan EU-EC-10009995381 | | 2021-09-14 | Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10735** | click or scan EU-EC-10009995183 | | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Jaundice (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10736** | click or scan EU-EC-10009995011 | | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **10737** | click or scan EU-EC-10009994904 | | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Female | Seizure (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10738** | click or scan EU-EC-10009994840 |  | 2021-09-14 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **10739** | click or scan EU-EC-10009994472 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10740** | click or scan EU-EC-10009994419 |  | 2021-09-14 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **10741** | click or scan EU-EC-10009994096 |  | 2021-09-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10742** | click or scan EU-EC-10009994086 |  | 2021-09-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10743** | click or scan EU-EC-10009994031 |  | 2021-09-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebellar stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10744** | click or scan EU-EC-10009993663 |  | 2021-09-14 | Non Healthcare Professional | EEA | Not Specified | Female | Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Meningoencephalitis herpetic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ophthalmic herpes zoster (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10745** | click or scan EU-EC-10009993661 |  | 2021-09-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10746** | click or scan EU-EC-10009993657 |  | 2021-09-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10747** | click or scan EU-EC-10009993388 |  | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10748** | click or scan EU-EC-10009992823 |  | 2021-09-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10749** | click or scan EU-EC-10009992554 |  | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10750** | click or scan EU-EC-10009992224 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10751** | click or scan EU-EC-10009992179 |  | 2021-09-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10752** | click or scan EU-EC-10009991729 |  | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nasopharyngitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10753** | click or scan EU-EC-10009991486 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10754** | click or scan EU-EC-10009990737 |  | 2021-09-14 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **10755** | click or scan EU-EC-10009990729 |  | 2021-09-14 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10756** | click or scan EU-EC-10009990402 |  | 2021-09-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10757 | click or scan EU-EC-10009990256 |  | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acidosis (0d - Fatal - **Results in Death**), Aspiration (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (0d - Fatal - **Results in Death**, Other Medically Important Condition), Discoloured vomit (0d - Fatal - **Results in Death**), Hypersensitivity (0d - Fatal - **Results in Death**), Pulmonary congestion (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 10758 | click or scan EU-EC-10009989850 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10759 | click or scan EU-EC-10009989769 |  | 2021-09-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 10760 | click or scan EU-EC-10009989556 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), No adverse event (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10761 | click or scan EU-EC-10009989193 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10762 | click or scan EU-EC-10009989178 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hangover (n/a - Unknown - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 10763 | click or scan EU-EC-10009989159 |  | 2021-09-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Caesarean section (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological decompensation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Petechiae (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pruritus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Purpura (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10764 | click or scan EU-EC-10009989108 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10765 | click or scan EU-EC-10009988956 |  | 2021-09-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10766** | click or scan EU-EC-10009988503 | | 2021-09-14 | Healthcare Professional | EEA | 65-85 Years | Female | Toxic epidermal necrolysis (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]), [ALLOPURINOL] (S - Hyperuricaemia - Drug withdrawn - [n/a - 300mg - Oral]) |
| **10767** | click or scan EU-EC-10009986481 | | 2021-09-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Insomnia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10768** | click or scan EU-EC-10009986412 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10769** | click or scan EU-EC-10009986332 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| **10770** | click or scan EU-EC-10009986318 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10771** | click or scan EU-EC-10009986215 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10772** | click or scan EU-EC-10009986093 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (2d - Fatal - **Results in Death**), Nausea (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10773** | click or scan EU-EC-10009985041 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Completed suicide (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed mood (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depression (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Overdose (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10774** | click or scan EU-EC-10009984867 | | 2021-09-13 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10775** | click or scan EU-EC-10009984847 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10776** | click or scan EU-EC-10009984756 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute chest syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), Bradycardia (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (1d - Fatal - **Results in Death**), Hypertriglyceridaemia (1d - Fatal - **Results in Death**), Mental status changes (1d - Fatal - **Results in Death**), Pneumonia staphylococcal (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sickle cell anaemia with crisis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vaginal haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10777** | click or scan EU-EC-10009984745 | | 2021-09-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Unknown - ), Liver disorder (n/a - Unknown - ), Malaise (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10778** | click or scan EU-EC-10009984726 | | 2021-09-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10779** | click or scan EU-EC-10009984696 | | 2021-09-13 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Multiple organ dysfunction syndrome (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **10780** | click or scan EU-EC-10009984484 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic infarction (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10781** | click or scan EU-EC-10009984334 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (1410min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (7h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (1410min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10782** | click or scan EU-EC-10009984176 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Congestive cardiomyopathy (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10783** | click or scan EU-EC-10009984013 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10784** | click or scan EU-EC-10009983914 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10785** | click or scan EU-EC-10009983891 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10786** | click or scan EU-EC-10009983827 |  | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **10787** | click or scan EU-EC-10009983781 |  | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10788** | click or scan EU-EC-10009983770 |  | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10789** | click or scan EU-EC-10009983745 |  | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriovenous malformation (3d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (3d - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (3d - Fatal - **Results in Death**), Death (3d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (46h - Fatal - **Results in Death**), Vomiting (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10790** | click or scan EU-EC-10009983658 |  | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10791** | click or scan EU-EC-10009983642 |  | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aphasia (1d - Fatal - **Results in Death**), Blood pressure immeasurable (1d - Fatal - **Results in Death**), Hypopnoea (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10792** | click or scan EU-EC-10009983633 |  | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (1d - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (1d - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Recovered/Resolved - ), Dyspnoea (1d - Unknown - Caused/Prolonged Hospitalisation), Nausea (1d - Unknown - Caused/Prolonged Hospitalisation), Vomiting (1d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10793** | click or scan EU-EC-10009983624 |  | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10794** | click or scan EU-EC-10009983593 |  | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10795** | click or scan EU-EC-10009983529 |  | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10796** | click or scan EU-EC-10009983429 | | 2021-09-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10797** | click or scan EU-EC-10009983360 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**), Death (9d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **10798** | click or scan EU-EC-10009983206 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10799** | click or scan EU-EC-10009982318 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **10800** | click or scan EU-EC-10009982306 | | 2021-09-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10801** | click or scan EU-EC-10009982265 | | 2021-09-13 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| **10802** | click or scan EU-EC-10009982119 | | 2021-09-13 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]) |
| **10803** | click or scan EU-EC-10009982108 | | 2021-09-13 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10804** | click or scan EU-EC-10009982055 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Alanine aminotransferase increased (n/a - Unknown - ), Albumin globulin ratio decreased (n/a - Unknown - ), Aspartate aminotransferase increased (n/a - Unknown - ), Blood albumin decreased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Unknown - ), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Lymphocyte count decreased (n/a - Unknown - ), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Neutrophil count increased (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count increased (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10805 | click or scan EU-EC-10009982001 | | 2021-09-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (10d - Fatal - **Results in Death**), Seizure (0d - Fatal - **Results in Death**) | VAXZEVRIA SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10806 | click or scan EU-EC-10009981960 | | 2021-09-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10807 | click or scan EU-EC-10009981917 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10808 | click or scan EU-EC-10009981861 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 10809 | click or scan EU-EC-10009981809 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malnutrition (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oral disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oral lichen planus (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Stomatitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 10810 | click or scan EU-EC-10009981707 | | 2021-09-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10811 | click or scan EU-EC-10009981690 | | 2021-09-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10812 | click or scan EU-EC-10009981687 | | 2021-09-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10813 | click or scan EU-EC-10009981667 | | 2021-09-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10814 | click or scan EU-EC-10009981537 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10815** | click or scan EU-EC-10009981304 |  | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **10816** | click or scan EU-EC-10009981255 |  | 2021-09-13 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| **10817** | click or scan EU-EC-10009981152 |  | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10818** | click or scan EU-EC-10009980784 |  | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Accidental exposure to product (n/a - Unknown - Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Pre-eclampsia (n/a - Unknown - Other Medically Important Condition), Stillbirth (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Streptococcal infection (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **10819** | click or scan EU-EC-10009980765 |  | 2021-09-13 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3 {DF} - n/a]) |
| **10820** | click or scan EU-EC-10009980762 |  | 2021-09-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Exercise tolerance decreased (n/a - Not Recovered/Not Resolved - ), Hiccups (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Tinnitus (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10821** | click or scan EU-EC-10009980761 |  | 2021-09-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10822** | click or scan EU-EC-10009980679 |  | 2021-09-13 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10823** | click or scan EU-EC-10009980589 |  | 2021-09-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Exercise tolerance decreased (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Influenza like illness (2d - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **10824** | click or scan EU-EC-10009980413 |  | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Feeding disorder (n/a - Fatal - **Results in Death**), Feeling hot (n/a - Unknown - ), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10825 | click or scan EU-EC-10009980247 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10826 | click or scan EU-EC-10009980010 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Unknown - ), Hydrocephalus (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10827 | click or scan EU-EC-10009980008 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10828 | click or scan EU-EC-10009979784 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Fatal - **Results in Death**), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**), Gastroenteritis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10829 | click or scan EU-EC-10009979659 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10830 | click or scan EU-EC-10009979487 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic valve stenosis (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Moaning (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10831 | click or scan EU-EC-10009979079 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Recovering/Resolving - Other Medically Important Condition), Urinary tract infection (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10832 | click or scan EU-EC-10009979054 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10833 | click or scan EU-EC-10009979042 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10834 | click or scan EU-EC-10009978862 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10835 | click or scan EU-EC-10009978796 | | 2021-09-13 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Chills (n/a - Unknown - ), Confusional state (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Life Threatening), Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Head injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Irregular breathing (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Miosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pupillary reflex impaired (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1min - .5mL - Intramuscular]) |
| 10836 | click or scan EU-EC-10009978065 | | 2021-09-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 10837 | click or scan EU-EC-10009977893 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10838 | click or scan EU-EC-10009977741 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10839 | click or scan EU-EC-10009977576 | | 2021-09-13 | Healthcare Professional | EEA | 65-85 Years | Female | Inflammatory marker increased (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 10840 | click or scan EU-EC-10009977185 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Idiopathic pulmonary fibrosis (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mouth breathing (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10841 | click or scan EU-EC-10009977174 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - ), Neoplasm progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10842 | click or scan EU-EC-10009976759 | | 2021-09-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 10843 | click or scan EU-EC-10009976299 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aberrant aortic arch (n/a - Fatal - **Results in Death**), Aortic aneurysm rupture (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Mediastinal haemorrhage (n/a - Fatal - **Results in Death**), Ventricular hypertrophy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10844 | click or scan EU-EC-10009975966 | | 2021-09-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Bradycardia (n/a - Unknown - Life Threatening), Cardiac arrest (5d - Fatal - **Results in Death**), Cerebral haemorrhage (5d - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Unknown - Life Threatening), Inflammatory marker increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 10845 | click or scan EU-EC-10009975610 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10846 | click or scan EU-EC-10009975600 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10847 | click or scan EU-EC-10009975493 | | 2021-09-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (69d - Fatal - **Results in Death**), Dizziness (69d - Fatal - **Results in Death**), Fatigue (69d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 10848 | click or scan EU-EC-10009975104 | | 2021-09-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | Sepsis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10849 | click or scan EU-EC-10009975093 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Unknown - ), Hyperkalaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10850 | click or scan EU-EC-10009975086 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Palpitations (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10851 | click or scan EU-EC-10009975085 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10852 | click or scan EU-EC-10009975073 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Chills (n/a - Unknown - ), Circulatory collapse (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Fall (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10853 | click or scan EU-EC-10009975051 | | 2021-09-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Dysphagia (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10854 | click or scan EU-EC-10009974569 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Unknown - ), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10855 | click or scan EU-EC-10009974567 | | 2021-09-13 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Herpes zoster (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Vaccination complication (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10856 | click or scan EU-EC-10009974315 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10857 | click or scan EU-EC-10009974314 | | 2021-09-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10858 | click or scan EU-EC-10009972581 | | 2021-09-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (17d - Fatal - **Results in Death**), Respiratory failure (17d - Fatal - **Results in Death**), Vaccination failure (17d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 10859 | click or scan EU-EC-10009971845 | | 2021-09-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 10860 | click or scan EU-EC-10009970375 | | 2021-09-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product contamination (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10861 | click or scan EU-EC-10009969224 | | 2021-09-11 | Healthcare Professional | EEA | More than 85 Years | Female | Coma (7d - Fatal - **Results in Death**), Vertebrobasilar stroke (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10862 | click or scan EU-EC-10009970226 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10863 | click or scan EU-EC-10009970213 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Eye inflammation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10864** | click or scan EU-EC-10009970207 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10865** | click or scan EU-EC-10009970127 | | 2021-09-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pemphigoid (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| **10866** | click or scan EU-EC-10009970062 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Blindness cortical (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Carotid artery occlusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Giant cell arteritis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Hypoperfusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Intermittent claudication (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tenderness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vasculitis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Visual impairment (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10867** | click or scan EU-EC-10009969928 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Capillary leak syndrome (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10868** | click or scan EU-EC-10009968418 | | 2021-09-10 | Healthcare Professional | Non EEA | Not Specified | Female | Foetal chromosome abnormality (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly), Foetal growth restriction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Foetal malformation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Hydrops foetalis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **10869** | click or scan EU-EC-10009968386 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10870** | click or scan EU-EC-10009968296 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia bacterial (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10871** | click or scan EU-EC-10009968210 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10872** | click or scan EU-EC-10009968137 | | 2021-09-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10873 | click or scan EU-EC-10009967962 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (1d - Fatal - **Results in Death**), Chills (1d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10874 | click or scan EU-EC-10009967943 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypersensitivity pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal atrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 10875 | click or scan EU-EC-10009967875 | | 2021-09-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematemesis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10876 | click or scan EU-EC-10009967573 | | 2021-09-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute lymphocytic leukaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Tooth infection (n/a - Recovering/Resolving - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10877 | click or scan EU-EC-10009966710 | | 2021-09-10 | Healthcare Professional | EEA | 18-64 Years | Male | Acute left ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10878 | click or scan EU-EC-10009966420 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Ventricular fibrillation (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10879 | click or scan EU-EC-10009966084 | | 2021-09-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10880 | click or scan EU-EC-10009965987 | | 2021-09-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac failure chronic (n/a - Fatal - **Results in Death**), Chronic kidney disease (n/a - Fatal - **Results in Death**), Chronic respiratory failure (n/a - Fatal - **Results in Death**), Disease progression (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10881 | click or scan EU-EC-10009965983 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10882 | click or scan EU-EC-10009965878 | | 2021-09-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10883 | click or scan EU-EC-10009965827 | | 2021-09-10 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (20d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 10884 | click or scan EU-EC-10009965544 | | 2021-09-10 | Healthcare Professional | EEA | 18-64 Years | Female | Aortic dissection (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 10885 | click or scan EU-EC-10009965511 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2{DF} - Intramuscular]) |
| 10886 | click or scan EU-EC-10009965510 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| 10887 | click or scan EU-EC-10009965509 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 10888 | click or scan EU-EC-10009965454 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 10889 | click or scan EU-EC-10009965416 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1{DF} - Intramuscular]) |
| 10890 | click or scan EU-EC-10009965413 | | 2021-09-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 10891 | click or scan EU-EC-10009965290 | | 2021-09-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Coagulopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cytokine release syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10892 | click or scan EU-EC-10009965236 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **10893** | click or scan EU-EC-10009964560 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Female | Hypercoagulation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **10894** | click or scan EU-EC-10009964541 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (8d - Fatal - **Results in Death**), Subarachnoid haemorrhage (0d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **10895** | click or scan EU-EC-10009964443 | | 2021-09-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Fall (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **10896** | click or scan EU-EC-10009964304 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **10897** | click or scan EU-EC-10009964256 | | 2021-09-10 | Healthcare Professional | Non EEA | Not Specified | Male | Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **10898** | click or scan EU-EC-10009964026 | | 2021-09-10 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10899** | click or scan EU-EC-10009964023 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10900** | click or scan EU-EC-10009964021 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10901** | click or scan EU-EC-10009963952 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **10902** | click or scan EU-EC-10009963911 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10903** | click or scan EU-EC-10009963909 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10904** | click or scan EU-EC-10009963880 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10905** | click or scan EU-EC-10009963876 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10906** | click or scan EU-EC-10009963875 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **10907** | click or scan EU-EC-10009963752 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10908** | click or scan EU-EC-10009963750 | | 2021-09-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10909** | click or scan EU-EC-10009963745 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10910** | click or scan EU-EC-10009963744 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (1h - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **10911** | click or scan EU-EC-10009963741 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **10912** | click or scan EU-EC-10009963739 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10913** | click or scan EU-EC-10009963561 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **10914** | click or scan EU-EC-10009963508 | | 2021-09-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **10915** | click or scan EU-EC-10009962436 | | 2021-09-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10916** | click or scan EU-EC-10009962429 | | 2021-09-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Blood electrolytes abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **10917** | click or scan EU-EC-10009961816 | | 2021-09-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **10918** | click or scan EU-EC-10009961679 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Epilepsy (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Malnutrition (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Postictal paralysis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertigo (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | APIXABAN [APIXABAN] (S - Atrial fibrillation, Drug intolerance - Drug withdrawn - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [15s - 1 {DF} - Intramuscular - More in ICSR]) |
| **10919** | click or scan EU-EC-10009961668 | | 2021-09-10 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Anencephaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Congenital central nervous system anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]), [CLOMIFENE CITRATE] (S - Polycystic ovaries - Unknown - [n/a - n/a - Transplacental]) |
| **10920** | click or scan EU-EC-10009961212 | | 2021-09-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10921 | click or scan EU-EC-10009960860 | | 2021-09-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Product contamination (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 10922 | click or scan EU-EC-10009960778 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 10923 | click or scan EU-EC-10009960711 | | 2021-09-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10924 | click or scan EU-EC-10009960596 | | 2021-09-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pruritus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 10925 | click or scan EU-EC-10009960593 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 10926 | click or scan EU-EC-10009959999 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Sepsis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 10927 | click or scan EU-EC-10009959894 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10928 | click or scan EU-EC-10009959824 | | 2021-09-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eating disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10929 | click or scan EU-EC-10009959802 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10930 | click or scan EU-EC-10009959726 | | 2021-09-10 | Healthcare Professional | EEA | 65-85 Years | Male | Subarachnoid haemorrhage (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 10931 | click or scan EU-EC-10009959492 | | 2021-09-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Agitation (n/a - Unknown - Other Medically Important Condition), Aortic stenosis (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Gaze palsy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10932 | click or scan EU-EC-10009959468 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10933 | click or scan EU-EC-10009959029 | | 2021-09-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Mental status changes (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 10934 | click or scan EU-EC-10009958893 | | 2021-09-10 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (27d - Fatal - **Results in Death**), COVID-19 pneumonia (27d - Fatal - **Results in Death**), Dyspnoea (27d - Fatal - **Results in Death**), Hypoxia (27d - Fatal - **Results in Death**), Pyrexia (27d - Fatal - **Results in Death**), SARS-CoV-2 test positive (27d - Fatal - **Results in Death**), Urinary tract infection (27d - Fatal - **Results in Death**), Vaccination failure (27d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .45mL - Intramuscular]) |
| 10935 | click or scan EU-EC-10009958865 | | 2021-09-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Haematoma (n/a - Fatal - **Results in Death**), Peripheral circulatory failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 10936 | click or scan EU-EC-10009957911 | | 2021-09-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10937 | click or scan EU-EC-10009957830 | | 2021-09-10 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Intracranial aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| 10938 | click or scan EU-EC-10009957349 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 10939 | click or scan EU-EC-10009956518 | | 2021-09-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10940 | click or scan EU-EC-10009956415 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10941 | click or scan EU-EC-10009955986 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 10942 | click or scan EU-EC-10009955675 | | 2021-09-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Vaccine breakthrough infection (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10943 | click or scan EU-EC-10009955442 | | 2021-09-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10944 | click or scan EU-EC-10009955365 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 10945 | click or scan EU-EC-10009955335 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10946 | click or scan EU-EC-10009955333 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10947 | click or scan EU-EC-10009955315 | | 2021-09-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**), Neoplasm malignant (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10948 | click or scan EU-EC-10009955257 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**), Decompressive craniectomy (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Platelet transfusion (n/a - Fatal - **Results in Death**), Thrombectomy (n/a - Fatal - **Results in Death**), Venous hypertension (n/a - Fatal - **Results in Death**), Vision blurred (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| 10949 | click or scan EU-EC-10009954934 | | 2021-09-09 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10950 | click or scan EU-EC-10009954307 | | 2021-09-09 | Healthcare Professional | EEA | 18-64 Years | Male | Overdose (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [BUPROPION HYDROCHLORIDE] (S - Product used for unknown indication - Unknown - [n/a - n/a - n/a]) |
| 10951 | click or scan EU-EC-10009953899 | | 2021-09-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10952 | click or scan EU-EC-10009953862 | | 2021-09-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 10953 | click or scan EU-EC-10009953796 | | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Male | Septic shock (24h - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10954 | click or scan EU-EC-10009953581 | | 2021-09-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia bacterial (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10955 | click or scan EU-EC-10009953345 | | 2021-09-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10956 | click or scan EU-EC-10009953296 | | 2021-09-09 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10957 | click or scan EU-EC-10009953280 | | 2021-09-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10958 | click or scan EU-EC-10009953213 | | 2021-09-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 10959 | click or scan EU-EC-10009953193 | | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **10960** | click or scan EU-EC-10009953153 |  | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [65d - 2 {DF} - Intramuscular]) |
| **10961** | click or scan EU-EC-10009953151 |  | 2021-09-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [83d - 2 {DF} - Intramuscular]) |
| **10962** | click or scan EU-EC-10009953125 |  | 2021-09-09 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [27d - 2 {DF} - Intramuscular]) |
| **10963** | click or scan EU-EC-10009953039 |  | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| **10964** | click or scan EU-EC-10009953035 |  | 2021-09-09 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| **10965** | click or scan EU-EC-10009952779 |  | 2021-09-09 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **10966** | click or scan EU-EC-10009951785 |  | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **10967** | click or scan EU-EC-10009951422 |  | 2021-09-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**), Jugular vein embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **10968** | click or scan EU-EC-10009951416 |  | 2021-09-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **10969** | click or scan EU-EC-10009950606 |  | 2021-09-09 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (95d - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Decreased appetite (95d - Fatal - **Results in Death**), Eastern Cooperative Oncology Group performance status worsened (95d - Fatal - **Results in Death**), Fall (95d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **10970** | click or scan EU-EC-10009950398 |  | 2021-09-09 | Non Healthcare Professional | Non EEA | Not Specified | Female | Congenital anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10971 | click or scan EU-EC-10009950389 | | 2021-09-09 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10972 | click or scan EU-EC-10009950120 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 10973 | click or scan EU-EC-10009950095 | | 2021-09-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 10974 | click or scan EU-EC-10009949950 | | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 10975 | click or scan EU-EC-10009949625 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10976 | click or scan EU-EC-10009949424 | | 2021-09-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved - ), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10977 | click or scan EU-EC-10009949196 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 10978 | click or scan EU-EC-10009949135 | | 2021-09-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10979 | click or scan EU-EC-10009949135 | | 2021-09-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10980 | click or scan EU-EC-10009949132 | | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 10981 | click or scan EU-EC-10009948980 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Menstrual disorder (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10982 | click or scan EU-EC-10009948178 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10983 | click or scan EU-EC-10009948168 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10984 | click or scan EU-EC-10009948167 | | 2021-09-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10985 | click or scan EU-EC-10009948163 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysphagia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10986 | click or scan EU-EC-10009948156 | | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10987 | click or scan EU-EC-10009948144 | | 2021-09-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dehydration (n/a - Recovering/Resolving - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 10988 | click or scan EU-EC-10009947752 | | 2021-09-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peritonitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10989 | click or scan EU-EC-10009947751 | | 2021-09-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 10990 | click or scan EU-EC-10009947406 | | 2021-09-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 10991 | click or scan EU-EC-10009947069 |  | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (63min - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10992 | click or scan EU-EC-10009947021 |  | 2021-09-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10993 | click or scan EU-EC-10009946795 |  | 2021-09-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Aneurysm (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 10994 | click or scan EU-EC-10009946563 |  | 2021-09-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral artery thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**), Troponin I increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 10995 | click or scan EU-EC-10009946439 |  | 2021-09-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 10996 | click or scan EU-EC-10009946153 |  | 2021-09-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Arrhythmia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Choking (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 10997 | click or scan EU-EC-10009945272 |  | 2021-09-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Micturition urgency (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 10998 | click or scan EU-EC-10009945242 |  | 2021-09-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular]) |
| 10999 | click or scan EU-EC-10009945143 |  | 2021-09-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11000 | click or scan EU-EC-10009942808 |  | 2021-09-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (0d - Fatal - **Results in Death**), Peripheral swelling (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11001** | click or scan EU-EC-10009942798 | | 2021-09-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11002** | click or scan EU-EC-10009942794 | | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Female | Hyperpyrexia (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **11003** | click or scan EU-EC-10009942783 | | 2021-09-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **11004** | click or scan EU-EC-10009942779 | | 2021-09-09 | Non Healthcare Professional | EEA | More than 85 Years | Male | Infarction (43d - Fatal - **Results in Death**), Thrombosis (43d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **11005** | click or scan EU-EC-10009942771 | | 2021-09-09 | Healthcare Professional | EEA | 65-85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Sopor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **11006** | click or scan EU-EC-10009944470 | | 2021-09-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Marasmus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11007** | click or scan EU-EC-10009943454 | | 2021-09-08 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **11008** | click or scan EU-EC-10009943303 | | 2021-09-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **11009** | click or scan EU-EC-10009942138 | | 2021-09-08 | Non Healthcare Professional | EEA | Not Specified | Male | Abdominal pain (n/a - Unknown - ), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injury (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mouth haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - ), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Serum sickness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - ), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11010** | click or scan EU-EC-10009941565 | | 2021-09-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), SARS-CoV-2 test positive (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11011** | click or scan EU-EC-10009941347 | | 2021-09-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **11012** | click or scan EU-EC-10009940979 | | 2021-09-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (0d - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vaccination site plaque (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11013** | click or scan EU-EC-10009940634 | | 2021-09-08 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11014** | click or scan EU-EC-10009940434 | | 2021-09-08 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11015** | click or scan EU-EC-10009939528 | | 2021-09-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11016** | click or scan EU-EC-10009939161 | | 2021-09-08 | Healthcare Professional | EEA | 18-64 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11017** | click or scan EU-EC-10009939054 | | 2021-09-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11018** | click or scan EU-EC-10009939024 | | 2021-09-08 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| **11019** | click or scan EU-EC-10009939007 | | 2021-09-08 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (9d - Fatal - **Results in Death**), Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 2 {DF} - Intramuscular]) |
| **11020** | click or scan EU-EC-10009938947 | | 2021-09-08 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [61d - 2 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11021 | click or scan EU-EC-10009938925 | | 2021-09-08 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11022 | click or scan EU-EC-10009938521 | | 2021-09-08 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11023 | click or scan EU-EC-10009938067 | | 2021-09-08 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11024 | click or scan EU-EC-10009937711 | | 2021-09-08 | Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Pleural effusion (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 11025 | click or scan EU-EC-10009937675 | | 2021-09-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (4d - Fatal - **Results in Death**), Arrhythmia (4d - Fatal - **Results in Death**), Asthenia (4d - Fatal - **Results in Death**), Coordination abnormal (4d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Nausea (4d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 11026 | click or scan EU-EC-10009937569 | | 2021-09-08 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11027 | click or scan EU-EC-10009937361 | | 2021-09-08 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 11028 | click or scan EU-EC-10009936761 | | 2021-09-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (20d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11029 | click or scan EU-EC-10009936760 | | 2021-09-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Abnormal behaviour (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Anxiety (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aphasia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Discoloured vomit (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Electric shock sensation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neurological symptom (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Off label use (n/a - Unknown - ), Pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Speech disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11030 | click or scan EU-EC-10009936307 | | 2021-09-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular]) |
| 11031 | click or scan EU-EC-10009935668 | | 2021-09-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypoaesthesia (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Pain (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11032 | click or scan EU-EC-10009935414 | | 2021-09-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cardiac stress test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Computerised tomogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Echocardiogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypertension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11033 | click or scan EU-EC-10009934001 | | 2021-09-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11034 | click or scan EU-EC-10009933578 | | 2021-09-08 | Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening), Death (0d - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30s - .5mL - Intramuscular]) |
| 11035 | click or scan EU-EC-10009933545 | | 2021-09-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11036 | click or scan EU-EC-10009933294 | | 2021-09-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Unknown - ), Pulmonary embolism (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 11037 | click or scan EU-EC-10009932870 | | 2021-09-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11038 | click or scan EU-EC-10009932416 | | 2021-09-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11039 | click or scan EU-EC-10009931935 | | 2021-09-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Intracranial aneurysm (4d - Fatal - **Results in Death**), Neck pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11040 | click or scan EU-EC-10009931884 | | 2021-09-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (119d - Fatal - **Results in Death**, Other Medically Important Condition), Death (119d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (119d - Fatal - **Results in Death**), Incomplete course of vaccination (119d - Fatal - **Results in Death**), Lymphadenopathy (119d - Fatal - **Results in Death**), Productive cough (119d - Fatal - **Results in Death**), Pulmonary thrombosis (119d - Fatal - **Results in Death**, Other Medically Important Condition), Swelling (119d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11041 | click or scan EU-EC-10009931695 | | 2021-09-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Fatal - **Results in Death**), Haematochezia (n/a - Unknown - Other Medically Important Condition), Haemoglobin decreased (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Infarction (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11042 | click or scan EU-EC-10009930884 | | 2021-09-08 | Healthcare Professional | EEA | More than 85 Years | Male | Hypoxia (16d - Fatal - **Results in Death**), Metabolic acidosis (16d - Fatal - **Results in Death**), Pulmonary embolism (16d - Fatal - **Results in Death**), Tachypnoea (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]), [QUETIAPINE, QUETIAPINE FUMARATE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 11043 | click or scan EU-EC-10009930808 | | 2021-09-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11044 | click or scan EU-EC-10009930737 | | 2021-09-08 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Bradycardia (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mg - Intramuscular]) |
| 11045 | click or scan EU-EC-10009930720 | | 2021-09-08 | Healthcare Professional | EEA | More than 85 Years | Male | Coombs positive haemolytic anaemia (9d - Fatal - **Results in Death**), Dyspnoea (9d - Fatal - **Results in Death**), Thrombocytopenia (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 11046 | click or scan EU-EC-10009929108 | | 2021-09-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bradycardia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11047 | click or scan EU-EC-10009928942 | | 2021-09-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11048 | click or scan EU-EC-10009928713 | | 2021-09-07 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Drowning (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11049 | click or scan EU-EC-10009927675 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11050 | click or scan EU-EC-10009927308 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hospice care (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11051 | click or scan EU-EC-10009926684 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11052 | click or scan EU-EC-10009926650 | | 2021-09-07 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - 1 {DF} - Intramuscular]) |
| 11053 | click or scan EU-EC-10009926589 | | 2021-09-07 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11054 | click or scan EU-EC-10009926564 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intradermal]) |
| 11055 | click or scan EU-EC-10009926555 | | 2021-09-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11056 | click or scan EU-EC-10009926536 | | 2021-09-07 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 11057 | click or scan EU-EC-10009926526 | | 2021-09-07 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [33d - 2 {DF} - Intramuscular]) |
| 11058 | click or scan EU-EC-10009926372 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11059 | click or scan EU-EC-10009925482 | | 2021-09-07 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Lung disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11060** | click or scan EU-EC-10009925480 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]), [TREPROSTINIL SODIUM] (S - Pulmonary hypertension - Not applicable - [185d - n/a - Nasal]) |
| **11061** | click or scan EU-EC-10009925160 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11062** | click or scan EU-EC-10009925100 | | 2021-09-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (6mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (6mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain in extremity (6mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vasculitis (6mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11063** | click or scan EU-EC-10009925004 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11064** | click or scan EU-EC-10009924730 | | 2021-09-07 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11065** | click or scan EU-EC-10009924568 | | 2021-09-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11066** | click or scan EU-EC-10009923892 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (3d - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **11067** | click or scan EU-EC-10009923690 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dehydration (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **11068** | click or scan EU-EC-10009923610 | | 2021-09-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11069** | click or scan EU-EC-10009923409 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11070** | click or scan EU-EC-10009922928 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11071** | click or scan EU-EC-10009922858 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Parkinson's disease (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11072** | click or scan EU-EC-10009922855 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11073** | click or scan EU-EC-10009922850 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11074** | click or scan EU-EC-10009922504 | | 2021-09-07 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11075** | click or scan EU-EC-10009922456 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), International normalised ratio increased (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), NON SPECIFIED ANTICOAGULANS [NOT AVAILABLE] (S - Myocardial infarction - Unknown - [n/a - n/a - n/a]) |
| **11076** | click or scan EU-EC-10009922450 | | 2021-09-07 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea exertional (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Malaise (n/a - Recovered/Resolved - ), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Recovered/Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11077** | click or scan EU-EC-10009922196 | | 2021-09-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysuria (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pigmentation disorder (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Skin swelling (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Visceral leishmaniasis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11078** | click or scan EU-EC-10009921715 | | 2021-09-07 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **11079** | click or scan EU-EC-10009921431 | | 2021-09-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Unknown - ), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11080** | click or scan EU-EC-10009921358 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| **11081** | click or scan EU-EC-10009920270 | | 2021-09-07 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11082** | click or scan EU-EC-10009919585 | | 2021-09-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - Other Medically Important Condition), Back pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11083** | click or scan EU-EC-10009919448 | | 2021-09-07 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Syncope (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11084** | click or scan EU-EC-10009919418 | | 2021-09-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11085** | click or scan EU-EC-10009919136 | | 2021-09-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11086** | click or scan EU-EC-10009918426 | | 2021-09-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11087** | click or scan EU-EC-10009917147 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11088** | click or scan EU-EC-10009916402 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11089 | click or scan EU-EC-10009915877 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Not Recovered/Not Resolved - ), Chest pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Hypertension (15min - Recovering/Resolving - ), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 11090 | click or scan EU-EC-10009915178 | | 2021-09-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Paresis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11091 | click or scan EU-EC-10009915146 | | 2021-09-07 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (4d - Fatal - **Results in Death**), Coma (4d - Fatal - **Results in Death**), Gaze palsy (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**), Subarachnoid haemorrhage (4d - Fatal - **Results in Death**), Vomiting (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11092 | click or scan EU-EC-10009914235 | | 2021-09-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11093 | click or scan EU-EC-10009913498 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11094 | click or scan EU-EC-10009912010 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11095 | click or scan EU-EC-10009911903 | | 2021-09-06 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product contamination (n/a - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11096 | click or scan EU-EC-10009911766 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Agonal respiration (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - ), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Hypoxia (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11097 | click or scan EU-EC-10009911630 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11098 | click or scan EU-EC-10009911614 | | 2021-09-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11099** | click or scan EU-EC-10009911086 | | 2021-09-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11100** | click or scan EU-EC-10009910919 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11101** | click or scan EU-EC-10009910630 | | 2021-09-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11102** | click or scan EU-EC-10009910452 | | 2021-09-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11103** | click or scan EU-EC-10009910376 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11104** | click or scan EU-EC-10009910374 | | 2021-09-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11105** | click or scan EU-EC-10009910077 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11106** | click or scan EU-EC-10009909480 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11107** | click or scan EU-EC-10009909471 | | 2021-09-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11108** | click or scan EU-EC-10009908842 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11109** | click or scan EU-EC-10009908836 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypertension (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11110 | click or scan EU-EC-10009908377 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11111 | click or scan EU-EC-10009908091 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Parkinson's disease (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11112 | click or scan EU-EC-10009907944 | | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 11113 | click or scan EU-EC-10009907022 | | 2021-09-06 | Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11114 | click or scan EU-EC-10009906470 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Blood urine present (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysuria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11115 | click or scan EU-EC-10009906209 | | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11116 | click or scan EU-EC-10009906191 | | 2021-09-06 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial fibrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11117 | click or scan EU-EC-10009906097 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11118 | click or scan EU-EC-10009905277 | | 2021-09-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Gravitational oedema (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11119 | click or scan EU-EC-10009905261 | | 2021-09-06 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11120 | click or scan EU-EC-10009905239 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11121 | click or scan EU-EC-10009905238 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11122 | click or scan EU-EC-10009905237 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11123 | click or scan EU-EC-10009905236 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11124 | click or scan EU-EC-10009905235 | | 2021-09-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11125 | click or scan EU-EC-10009905192 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11126 | click or scan EU-EC-10009905189 | | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11127 | click or scan EU-EC-10009904890 | | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Dependence on respirator (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11128 | click or scan EU-EC-10009904635 | | 2021-09-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11129** | click or scan EU-EC-10009904629 |  | 2021-09-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11130** | click or scan EU-EC-10009904623 |  | 2021-09-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11131** | click or scan EU-EC-10009904622 |  | 2021-09-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Rash (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11132** | click or scan EU-EC-10009904620 |  | 2021-09-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11133** | click or scan EU-EC-10009904429 |  | 2021-09-06 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dementia (n/a - Unknown - Disabling, Other Medically Important Condition), Helplessness (n/a - Unknown - Disabling), Mobility decreased (n/a - Unknown - Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11134** | click or scan EU-EC-10009903756 |  | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11135** | click or scan EU-EC-10009903652 |  | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11136** | click or scan EU-EC-10009903288 |  | 2021-09-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (2d - Recovered/Resolved - ), Dyspnoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (16d - Fatal - **Results in Death**), Urinary tract infection (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **11137** | click or scan EU-EC-10009902889 |  | 2021-09-06 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11138** | click or scan EU-EC-10009902867 |  | 2021-09-06 | Healthcare Professional | EEA | Not Specified | Not Specified | Back pain (4d - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Dyspnoea (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11139** | click or scan EU-EC-10009902820 | | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11140** | click or scan EU-EC-10009902209 | | 2021-09-06 | Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulse absent (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **11141** | click or scan EU-EC-10009902180 | | 2021-09-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Illness (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11142** | click or scan EU-EC-10009902064 | | 2021-09-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11143** | click or scan EU-EC-10009901775 | | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **11144** | click or scan EU-EC-10009901674 | | 2021-09-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Cardiac discomfort (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), End stage renal disease (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Peripheral vascular disorder (n/a - Fatal - **Results in Death**), Skin ulcer (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **11145** | click or scan EU-EC-10009901620 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abscess (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac aneurysm (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haematoma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Transient ischaemic attack (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11146** | click or scan EU-EC-10009901534 | | 2021-09-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Troponin T increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [OXALIPLATIN] (S - Neoplasm malignant - Unknown - [n/a - n/a - n/a]), [TEGAFUR, GIMERACIL, OTERACIL POTASSIUM] (S - Neoplasm malignant - Unknown - [n/a - n/a - n/a]) |
| **11147** | click or scan EU-EC-10009901335 | | 2021-09-06 | Healthcare Professional | EEA | 65-85 Years | Female | Apnoea (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mydriasis (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (6d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **11148** | click or scan EU-EC-10009900835 | | 2021-09-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), XELJANZ [TOFACITINIB, TOFACITINIB CITRATE] (S - Rheumatoid arthritis - Not applicable - [n/a - 10mg - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11149 | click or scan EU-EC-10009900624 |  | 2021-09-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 11150 | click or scan EU-EC-10009899221 |  | 2021-09-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11151 | click or scan EU-EC-10009897716 |  | 2021-09-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11152 | click or scan EU-EC-10009897713 |  | 2021-09-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal distension (3d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Haematoma (3d - Fatal - **Results in Death**), Sopor (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11153 | click or scan EU-EC-10009896096 |  | 2021-09-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11154 | click or scan EU-EC-10009895967 |  | 2021-09-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11155 | click or scan EU-EC-10009895525 |  | 2021-09-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11156 | click or scan EU-EC-10009894853 |  | 2021-09-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Wheezing (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11157 | click or scan EU-EC-10009894799 |  | 2021-09-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 11158 | click or scan EU-EC-10009894219 |  | 2021-09-04 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (18d - Fatal - **Results in Death**), Gait inability (18d - Fatal - **Results in Death**), Hallucination (18d - Fatal - **Results in Death**), Leukocytosis (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11159 | click or scan EU-EC-10009894163 | | 2021-09-04 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11160 | click or scan EU-EC-10009894051 | | 2021-09-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 11161 | click or scan EU-EC-10009894846 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (1d - Unknown - Other Medically Important Condition), Chest pain (1d - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Unknown - ), Hypotension (1d - Unknown - ), Loss of consciousness (1d - Unknown - Other Medically Important Condition), Oxygen saturation decreased (1d - Unknown - ), Pulseless electrical activity (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11162 | click or scan EU-EC-10009894381 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 11163 | click or scan EU-EC-10009893655 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cold sweat (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11164 | click or scan EU-EC-10009893405 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination complication (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 11165 | click or scan EU-EC-10009893208 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11166 | click or scan EU-EC-10009893106 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11167 | click or scan EU-EC-10009893101 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11168 | click or scan EU-EC-10009892809 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11169 | click or scan EU-EC-10009892803 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11170 | click or scan EU-EC-10009892801 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11171 | click or scan EU-EC-10009892780 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11172 | click or scan EU-EC-10009892746 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11173 | click or scan EU-EC-10009892659 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Female | Aneurysm (1d - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Hypertensive crisis (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11174 | click or scan EU-EC-10009892491 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Unknown - Life Threatening, Other Medically Important Condition), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 11175 | click or scan EU-EC-10009892452 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11176 | click or scan EU-EC-10009892414 | | 2021-09-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Hypotension (1d - Fatal - **Results in Death**), Respiration abnormal (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**), Vaccination complication (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11177 | click or scan EU-EC-10009892349 | | 2021-09-03 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11178 | click or scan EU-EC-10009892347 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11179 | click or scan EU-EC-10009892331 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11180 | click or scan EU-EC-10009892278 | | 2021-09-03 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11181 | click or scan EU-EC-10009892235 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mg - Unknown]) |
| 11182 | click or scan EU-EC-10009892207 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11183 | click or scan EU-EC-10009892184 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (1d - Fatal - **Results in Death**), Myocardial ischaemia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11184 | click or scan EU-EC-10009892166 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11185 | click or scan EU-EC-10009892155 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11186 | click or scan EU-EC-10009892150 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11187 | click or scan EU-EC-10009892149 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Discomfort (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11188 | click or scan EU-EC-10009892141 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Choking (1d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11189 | click or scan EU-EC-10009892130 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11190 | click or scan EU-EC-10009891885 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cold sweat (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11191 | click or scan EU-EC-10009891870 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [2mo - .5mL - Intramuscular]) |
| 11192 | click or scan EU-EC-10009891726 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bronchitis (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11193 | click or scan EU-EC-10009891723 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11194 | click or scan EU-EC-10009891696 | | 2021-09-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 11195 | click or scan EU-EC-10009891687 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11196 | click or scan EU-EC-10009891674 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11197 | click or scan EU-EC-10009891622 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (9d - Fatal - **Results in Death**), Fatigue (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11198 | click or scan EU-EC-10009891465 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Blood pressure decreased (5d - Fatal - **Results in Death**), Fatigue (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - ), Muscular weakness (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (5d - Fatal - **Results in Death**), Syncope (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |
| 11199 | click or scan EU-EC-10009891372 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic thrombosis (n/a - Fatal - **Results in Death**), Chest pain (1d - Unknown - Other Medically Important Condition), Chills (3d - Unknown - ), Headache (1d - Unknown - ), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (3d - Unknown - ), Palpitations (1d - Unknown - Other Medically Important Condition), Vomiting (3d - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11200** | click or scan EU-EC-10009891223 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11201** | click or scan EU-EC-10009891188 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| **11202** | click or scan EU-EC-10009891176 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11203** | click or scan EU-EC-10009891137 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11204** | click or scan EU-EC-10009891046 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fibrin D dimer (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mesenteric artery thrombosis (n/a - Unknown - Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral artery occlusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11205** | click or scan EU-EC-10009891042 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Hydrocephalus (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11206** | click or scan EU-EC-10009891035 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11207** | click or scan EU-EC-10009890829 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11208** | click or scan EU-EC-10009890808 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11209** | click or scan EU-EC-10009890517 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11210** | click or scan EU-EC-10009890363 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Agitation (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Gaze palsy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11211 | click or scan EU-EC-10009890172 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11212 | click or scan EU-EC-10009890017 | | 2021-09-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (1d - Fatal - **Results in Death**), Altered state of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Faeces discoloured (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11213 | click or scan EU-EC-10009889918 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chills (1d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**), Pyrexia (1d - Recovered/Resolved - ), Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 11214 | click or scan EU-EC-10009889199 | | 2021-09-03 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11215 | click or scan EU-EC-10009888806 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blister (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11216 | click or scan EU-EC-10009888786 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic arteriosclerosis (1d - Fatal - **Results in Death**), Chronic kidney disease (1d - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (1d - Fatal - **Results in Death**), Renal infarct (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11217 | click or scan EU-EC-10009888769 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiovascular disorder (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11218 | click or scan EU-EC-10009888610 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11219 | click or scan EU-EC-10009888606 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11220 | click or scan EU-EC-10009888500 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11221 | click or scan EU-EC-10009888498 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11222 | click or scan EU-EC-10009888441 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - ), Pleural effusion (n/a - Fatal - **Results in Death**), Productive cough (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Vaccination site pain (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11223 | click or scan EU-EC-10009888380 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Epistaxis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11224 | click or scan EU-EC-10009888376 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11225 | click or scan EU-EC-10009888370 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11226 | click or scan EU-EC-10009888368 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Nausea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11227 | click or scan EU-EC-10009888366 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11228 | click or scan EU-EC-10009888353 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Streptococcus test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [3d - n/a - Intramuscular]) |
| 11229 | click or scan EU-EC-10009888304 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11230 | click or scan EU-EC-10009888244 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Female | Pancreatitis acute (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11231 | click or scan EU-EC-10009888179 | | 2021-09-03 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 2 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11232 | click or scan EU-EC-10009888168 | | 2021-09-03 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2 {DF} - Intramuscular]) |
| 11233 | click or scan EU-EC-10009888158 | | 2021-09-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**), Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - 1 {DF} - Intramuscular]) |
| 11234 | click or scan EU-EC-10009888157 | | 2021-09-03 | Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (11d - Fatal - **Results in Death**), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - 1 {DF} - Intramuscular]) |
| 11235 | click or scan EU-EC-10009888156 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**), General physical health deterioration (6d - Fatal - **Results in Death**), Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - 1 {DF} - Intramuscular]) |
| 11236 | click or scan EU-EC-10009888153 | | 2021-09-03 | Healthcare Professional | EEA | More than 85 Years | Female | Adult failure to thrive (9d - Fatal - **Results in Death**), COVID-19 (24d - Fatal - **Results in Death**), Vaccination failure (24d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 11237 | click or scan EU-EC-10009888124 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 11238 | click or scan EU-EC-10009888111 | | 2021-09-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 11239 | click or scan EU-EC-10009888087 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11240 | click or scan EU-EC-10009888006 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (14d - Fatal - **Results in Death**), Cardiac arrest (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Fatal - **Results in Death**), Dizziness (14d - Fatal - **Results in Death**), Meniere's disease (14d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (14d - Fatal - **Results in Death**), Vomiting (14d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |
| 11241 | click or scan EU-EC-10009887736 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rhinorrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11242 | click or scan EU-EC-10009887613 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11243 | click or scan EU-EC-10009887607 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (104d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11244 | click or scan EU-EC-10009887243 | | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11245 | click or scan EU-EC-10009887178 | | 2021-09-03 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Underdose (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11246 | click or scan EU-EC-10009887175 | | 2021-09-03 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Underdose (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11247 | click or scan EU-EC-10009887163 | | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11248 | click or scan EU-EC-10009887075 | | 2021-09-03 | Healthcare Professional | EEA | 18-64 Years | Male | Irritability (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 11249 | click or scan EU-EC-10009886452 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11250 | click or scan EU-EC-10009886437 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11251 | click or scan EU-EC-10009886435 | | 2021-09-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11252 | click or scan EU-EC-10009885681 | | 2021-09-03 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11253 | click or scan EU-EC-10009885521 |  | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11254 | click or scan EU-EC-10009885226 |  | 2021-09-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthma (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 11255 | click or scan EU-EC-10009885105 |  | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11256 | click or scan EU-EC-10009885104 |  | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |
| 11257 | click or scan EU-EC-10009884760 |  | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 11258 | click or scan EU-EC-10009884517 |  | 2021-09-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - n/a]), [LEUPRORELIN, LEUPRORELIN ACETATE] (S - Prostate cancer - Not applicable - [n/a - 1{DF} - Subcutaneous]) |
| 11259 | click or scan EU-EC-10009883169 |  | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11260 | click or scan EU-EC-10009883147 |  | 2021-09-03 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vascular stent thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 11261 | click or scan EU-EC-10009882492 |  | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11262 | click or scan EU-EC-10009882491 |  | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11263 | click or scan EU-EC-10009882480 |  | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11264 | click or scan EU-EC-10009881232 | | 2021-09-03 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Unknown - ), Hypoxia (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11265 | click or scan EU-EC-10009881183 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Duodenal ulcer haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (S - Pulmonary embolism - Drug withdrawn - [n/a - n/a - n/a]) |
| 11266 | click or scan EU-EC-10009881089 | | 2021-09-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11267 | click or scan EU-EC-10009880978 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (5d - Unknown - Caused/Prolonged Hospitalisation), Hospice care (3d - Unknown - ), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia (5d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11268 | click or scan EU-EC-10009880926 | | 2021-09-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11269 | click or scan EU-EC-10009880783 | | 2021-09-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11270 | click or scan EU-EC-10009880272 | | 2021-09-03 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiogenic shock (26d - Fatal - **Results in Death**), Dyspnoea (26d - Fatal - **Results in Death**), Headache (26d - Fatal - **Results in Death**), Pulmonary embolism (26d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11271 | click or scan EU-EC-10009880334 | | 2021-09-02 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11272 | click or scan EU-EC-10009879411 | | 2021-09-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 11273 | click or scan EU-EC-10009879252 | | 2021-09-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11274 | click or scan EU-EC-10009878786 | | 2021-09-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Dyskinesia (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11275 | click or scan EU-EC-10009878110 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Male | Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11276 | click or scan EU-EC-10009876588 | | 2021-09-02 | Non Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate decreased (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 11277 | click or scan EU-EC-10009876209 | | 2021-09-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11278 | click or scan EU-EC-10009875161 | | 2021-09-02 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiomegaly (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Palpitations (n/a - Fatal - **Results in Death**), Product administered to patient of inappropriate age (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11279 | click or scan EU-EC-10009874946 | | 2021-09-02 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11280 | click or scan EU-EC-10009874831 | | 2021-09-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (14d - Fatal - **Results in Death**, Life Threatening), Drug ineffective (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11281 | click or scan EU-EC-10009873272 | | 2021-09-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11282 | click or scan EU-EC-10009873241 | | 2021-09-02 | Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11283 | click or scan EU-EC-10009873225 | | 2021-09-02 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11284 | click or scan EU-EC-10009873217 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - 1 {DF} - Intramuscular]) |
| 11285 | click or scan EU-EC-10009873208 | | 2021-09-02 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 11286 | click or scan EU-EC-10009873179 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11287 | click or scan EU-EC-10009873176 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11288 | click or scan EU-EC-10009873140 | | 2021-09-02 | Healthcare Professional | EEA | 65-85 Years | Male | Acquired haemophilia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 11289 | click or scan EU-EC-10009873070 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 11290 | click or scan EU-EC-10009873064 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 11291 | click or scan EU-EC-10009873058 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary oedema (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 11292 | click or scan EU-EC-10009872088 | | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11293 | click or scan EU-EC-10009871561 |  | 2021-09-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Lip and/or oral cavity cancer (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11294 | click or scan EU-EC-10009871348 |  | 2021-09-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11295 | click or scan EU-EC-10009871265 |  | 2021-09-02 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Hepatic function abnormal (n/a - Unknown - ), Neoplasm progression (n/a - Unknown - ), Portal vein thrombosis (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), FULVESTRANT [FULVESTRANT] (S - Hormone receptor positive breast cancer - Unknown - [n/a - n/a - n/a]), IBRANCE [PALBOCICLIB] (S - Hormone receptor positive breast cancer - Unknown - [n/a - n/a - Oral]) |
| 11296 | click or scan EU-EC-10009871086 |  | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11297 | click or scan EU-EC-10009871057 |  | 2021-09-02 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11298 | click or scan EU-EC-10009870562 |  | 2021-09-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Computerised tomogram (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11299 | click or scan EU-EC-10009870310 |  | 2021-09-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperthermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11300 | click or scan EU-EC-10009869943 |  | 2021-09-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site erythema (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11301 | click or scan EU-EC-10009869646 |  | 2021-09-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11302 | click or scan EU-EC-10009869128 |  | 2021-09-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11303 | click or scan EU-EC-10009869077 |  | 2021-09-02 | Healthcare Professional | EEA | 65-85 Years | Male | Renal mass (5d - Fatal - **Results in Death**), Sepsis (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3uL - Intramuscular]) |
| 11304 | click or scan EU-EC-10009868760 |  | 2021-09-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11305 | click or scan EU-EC-10009868756 |  | 2021-09-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11306 | click or scan EU-EC-10009868568 |  | 2021-09-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Consciousness fluctuating (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11307 | click or scan EU-EC-10009868368 |  | 2021-09-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous]) |
| 11308 | click or scan EU-EC-10009868328 |  | 2021-09-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 11309 | click or scan EU-EC-10009868302 |  | 2021-09-02 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cachexia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dementia (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11310 | click or scan EU-EC-10009868069 |  | 2021-09-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (4d - Fatal - **Results in Death**), Cerebrovascular accident (1d - Fatal - **Results in Death**), Coma (4d - Fatal - **Results in Death**), Decreased appetite (1d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Dyspepsia (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Fibrin D dimer increased (4d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Loss of consciousness (4d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Unresponsive to stimuli (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11311 | click or scan EU-EC-10009867875 |  | 2021-09-02 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 11312 | click or scan EU-EC-10009867137 |  | 2021-09-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (12d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11313 | click or scan EU-EC-10009866957 |  | 2021-09-02 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 11314 | click or scan EU-EC-10009866923 |  | 2021-09-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (1d - Fatal - **Results in Death**), Arteriosclerosis coronary artery (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**), Head discomfort (9d - Fatal - **Results in Death**), Hyperhidrosis (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Oral discomfort (9d - Fatal - **Results in Death**), Pain in extremity (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11315 | click or scan EU-EC-10009866909 |  | 2021-09-02 | Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11316 | click or scan EU-EC-10009866453 |  | 2021-09-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11317 | click or scan EU-EC-10009866046 |  | 2021-09-02 | Non Healthcare Professional | EEA | Not Specified | Male | Abdominal pain (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11318 | click or scan EU-EC-10009865162 |  | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11319 | click or scan EU-EC-10009865082 |  | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11320 | click or scan EU-EC-10009864001 |  | 2021-09-01 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11321 | click or scan EU-EC-10009863377 |  | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 11322 | click or scan EU-EC-10009863190 |  | 2021-09-01 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (6d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11323 | click or scan EU-EC-10009863140 | | 2021-09-01 | Healthcare Professional | EEA | More than 85 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11324 | click or scan EU-EC-10009863071 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11325 | click or scan EU-EC-10009863070 | | 2021-09-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11326 | click or scan EU-EC-10009862934 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (12d - Unknown - ), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11327 | click or scan EU-EC-10009862325 | | 2021-09-01 | Non Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11328 | click or scan EU-EC-10009862111 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 11329 | click or scan EU-EC-10009861857 | | 2021-09-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (13d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11330 | click or scan EU-EC-10009861422 | | 2021-09-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11331 | click or scan EU-EC-10009861378 | | 2021-09-01 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11332 | click or scan EU-EC-10009861086 | | 2021-09-01 | Non Healthcare Professional | EEA | 18-64 Years | Female | Metastases to lung (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11333 | click or scan EU-EC-10009859878 |  | 2021-09-01 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular]) |
| 11334 | click or scan EU-EC-10009859839 |  | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11335 | click or scan EU-EC-10009859836 |  | 2021-09-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11336 | click or scan EU-EC-10009859805 |  | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11337 | click or scan EU-EC-10009859774 |  | 2021-09-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11338 | click or scan EU-EC-10009859715 |  | 2021-09-01 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11339 | click or scan EU-EC-10009859708 |  | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11340 | click or scan EU-EC-10009859620 |  | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Female | Condition aggravated (29d - Fatal - **Results in Death**), Diarrhoea (n/a - Recovering/Resolving - ), Disturbance in attention (29d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Unknown - ), Hypokalaemia (n/a - Unknown - ), Nephrotic syndrome (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), EXFORGE 10 MG/160 MG FILM-COATED TABLETS [VALSARTAN, AMLODIPINE] (S - n/a - Not applicable - [n/a - 1{DF} - Oral]), [HYDROCHLOROTHIAZIDE] (S - n/a - Not applicable - [n/a - 1{DF} - Oral]) |
| 11341 | click or scan EU-EC-10009859610 |  | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11342 | click or scan EU-EC-10009859609 |  | 2021-09-01 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11343 | click or scan EU-EC-10009859582 | | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - n/a]), PERTUZUMAB [PERTUZUMAB] (S - n/a - Not applicable - [n/a - n/a - n/a]), TRASTUZUMAB [TRASTUZUMAB] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 11344 | click or scan EU-EC-10009859429 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Intracardiac thrombus (171d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11345 | click or scan EU-EC-10009859354 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Ageusia (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11346 | click or scan EU-EC-10009858742 | | 2021-09-01 | Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Personality change (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 11347 | click or scan EU-EC-10009858720 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11348 | click or scan EU-EC-10009858716 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid retention (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Weight increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11349 | click or scan EU-EC-10009858540 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Decreased appetite (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11350 | click or scan EU-EC-10009858276 | | 2021-09-01 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11351 | click or scan EU-EC-10009858224 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11352 | click or scan EU-EC-10009858210 | | 2021-09-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 11353 | click or scan EU-EC-10009858182 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 11354 | click or scan EU-EC-10009857931 | | 2021-09-01 | Healthcare Professional | EEA | 18-64 Years | Female | Anosmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysgeusia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Emphysema (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Eye discharge (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Eye pain (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Eyelid margin crusting (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Eyelid ptosis (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Foreign body sensation in eyes (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic steatosis (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ocular hyperaemia (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory disorder (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11355 | click or scan EU-EC-10009857662 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 11356 | click or scan EU-EC-10009857322 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agonal respiration (n/a - Unknown - Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11357 | click or scan EU-EC-10009857292 | | 2021-09-01 | Healthcare Professional | EEA | More than 85 Years | Not Specified | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11358 | click or scan EU-EC-10009857288 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11359 | click or scan EU-EC-10009857080 | | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11360 | click or scan EU-EC-10009856844 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Illness (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic stroke (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vision blurred (109d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11361 | click or scan EU-EC-10009856798 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - ), Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia mycoplasmal (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11362 | click or scan EU-EC-10009856755 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11363 | click or scan EU-EC-10009856749 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11364 | click or scan EU-EC-10009856746 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (162d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11365 | click or scan EU-EC-10009856676 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), General physical health deterioration (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Muscular weakness (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11366 | click or scan EU-EC-10009856523 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Intestinal perforation (24d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (24d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 11367 | click or scan EU-EC-10009856480 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11368 | click or scan EU-EC-10009856273 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11369** | click or scan EU-EC-10009856183 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Embolic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gaze palsy (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infarction (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle rigidity (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle twitching (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Partial seizures (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Status epilepticus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (60d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **11370** | click or scan EU-EC-10009856180 | | 2021-09-01 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11371** | click or scan EU-EC-10009855943 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - ), Flushing (n/a - Unknown - ), Pulmonary hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11372** | click or scan EU-EC-10009855639 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (5d - Fatal - **Results in Death**), Death (5d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (5d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11373** | click or scan EU-EC-10009855622 | | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Male | Breath sounds abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11374** | click or scan EU-EC-10009855536 | | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Female | Bronchitis (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11375** | click or scan EU-EC-10009855441 | | 2021-09-01 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11376** | click or scan EU-EC-10009855440 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11377** | click or scan EU-EC-10009855235 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11378 | click or scan EU-EC-10009855178 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (190d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (190d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11379 | click or scan EU-EC-10009854934 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacteraemia (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Central venous catheterisation (33d - Fatal - **Results in Death**), Death (33d - Fatal - **Results in Death**, Other Medically Important Condition), Disease recurrence (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pemphigoid (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11380 | click or scan EU-EC-10009854926 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11381 | click or scan EU-EC-10009854916 | | 2021-09-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 11382 | click or scan EU-EC-10009854896 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (76d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Bronchopulmonary aspergillosis (76d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (76d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (76d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (76d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11383 | click or scan EU-EC-10009854678 | | 2021-09-01 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11384 | click or scan EU-EC-10009854672 | | 2021-09-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11385 | click or scan EU-EC-10009854604 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11386 | click or scan EU-EC-10009854550 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11387 | click or scan EU-EC-10009854213 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11388 | click or scan EU-EC-10009854186 | | 2021-09-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11389 | click or scan EU-EC-10009854063 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthritis (n/a - Fatal - **Results in Death**, Life Threatening), Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening), Death (3d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Pain (n/a - Fatal - **Results in Death**, Life Threatening), Rash (n/a - Fatal - **Results in Death**, Life Threatening), Swelling (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11390 | click or scan EU-EC-10009854060 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (70d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11391 | click or scan EU-EC-10009854055 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11392 | click or scan EU-EC-10009854040 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11393 | click or scan EU-EC-10009853674 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anal incontinence (10d - Fatal - **Results in Death**), Fatigue (10d - Fatal - **Results in Death**), Feeling abnormal (10d - Fatal - **Results in Death**), Pain (10d - Fatal - **Results in Death**), Secretion discharge (10d - Fatal - **Results in Death**), Vision blurred (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 11394 | click or scan EU-EC-10009853598 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ocular hyperaemia (n/a - Fatal - **Results in Death**), Pemphigoid (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11395 | click or scan EU-EC-10009853581 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arterial rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Unknown - Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11396 | click or scan EU-EC-10009853557 | | 2021-09-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11397 | click or scan EU-EC-10009853366 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11398 | click or scan EU-EC-10009853365 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11399 | click or scan EU-EC-10009853264 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Epilepsy (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Factor V Leiden mutation (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Seizure (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Superior sagittal sinus thrombosis (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11400 | click or scan EU-EC-10009853235 | | 2021-09-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (9d - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11401 | click or scan EU-EC-10009852989 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11402 | click or scan EU-EC-10009852974 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Influenza like illness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11403 | click or scan EU-EC-10009852890 | | 2021-09-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11404 | click or scan EU-EC-10009852352 | | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11405 | click or scan EU-EC-10009852344 | | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11406 | click or scan EU-EC-10009852341 |  | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cold sweat (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11407 | click or scan EU-EC-10009852186 |  | 2021-09-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dermatosis (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11408 | click or scan EU-EC-10009852099 |  | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (131d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11409 | click or scan EU-EC-10009851993 |  | 2021-09-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11410 | click or scan EU-EC-10009851829 |  | 2021-09-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11411 | click or scan EU-EC-10009851577 |  | 2021-09-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Inappropriate schedule of product administration (n/a - Unknown - ), Palpitations (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11412 | click or scan EU-EC-10009851295 |  | 2021-09-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11413 | click or scan EU-EC-10009850965 |  | 2021-09-01 | Healthcare Professional | EEA | 65-85 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 11414 | click or scan EU-EC-10009850313 |  | 2021-09-01 | Healthcare Professional | EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 11415 | click or scan EU-EC-10009850096 |  | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11416 | click or scan EU-EC-10009849909 |  | 2021-08-31 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pain in extremity (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11417 | click or scan EU-EC-10009849861 |  | 2021-08-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11418 | click or scan EU-EC-10009849645 |  | 2021-08-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11419 | click or scan EU-EC-10009849602 |  | 2021-08-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11420 | click or scan EU-EC-10009849552 |  | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11421 | click or scan EU-EC-10009848555 |  | 2021-08-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11422 | click or scan EU-EC-10009847636 |  | 2021-08-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (530min - Recovered/Resolved - ), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (580min - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11423 | click or scan EU-EC-10009847630 |  | 2021-08-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Drowning (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Thrombotic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11424 | click or scan EU-EC-10009847139 |  | 2021-08-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Hyponatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (9d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11425 | click or scan EU-EC-10009846241 |  | 2021-08-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11426 | click or scan EU-EC-10009846108 |  | 2021-08-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Apnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11427 | click or scan EU-EC-10009846094 | | 2021-08-31 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (8d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Rhinorrhoea (n/a - Unknown - ), Vomiting (3d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11428 | click or scan EU-EC-10009846064 | | 2021-08-31 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11429 | click or scan EU-EC-10009845501 | | 2021-08-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bronchopneumopathy (n/a - Recovering/Resolving - ), Cardiac flutter (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Septic shock (13d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11430 | click or scan EU-EC-10009845472 | | 2021-08-31 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 11431 | click or scan EU-EC-10009845467 | | 2021-08-31 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11432 | click or scan EU-EC-10009845452 | | 2021-08-31 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 11433 | click or scan EU-EC-10009845445 | | 2021-08-31 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 11434 | click or scan EU-EC-10009845442 | | 2021-08-31 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11435 | click or scan EU-EC-10009845424 | | 2021-08-31 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11436** | click or scan EU-EC-10009845397 | | 2021-08-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN CALCIUM, EZETIMIBE, ATORVASTATIN, EZETIMIBE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BUSPIRONE HYDROCHLORIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ENOXAPARIN SODIUM] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FENTANYL] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOCLOPRAMIDE, METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PHLOROGLUCINOL DIHYDRATE, PHLOROGLUCINOL, TRIMETHYLPHLOROGLUCINOL, TRIMETHYLPHLOROGLUCINOL, PHLOROGLUCINOL DIHYDRATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POLYETHYLENE GLYCOL DISTEARATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [RISEDRONATE SODIUM] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]) |
| **11437** | click or scan EU-EC-10009845306 | | 2021-08-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11438** | click or scan EU-EC-10009845207 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Throat irritation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11439** | click or scan EU-EC-10009845192 | | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11440** | click or scan EU-EC-10009845072 | | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11441 | click or scan EU-EC-10009844982 |  | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Unknown - ), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11442 | click or scan EU-EC-10009844828 |  | 2021-08-31 | Non Healthcare Professional | EEA | More than 85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 11443 | click or scan EU-EC-10009844389 |  | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Alcohol poisoning (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11444 | click or scan EU-EC-10009844219 |  | 2021-08-31 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11445 | click or scan EU-EC-10009844018 |  | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Posturing (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 11446 | click or scan EU-EC-10009843753 |  | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11447 | click or scan EU-EC-10009843742 |  | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Conjunctivitis (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Rash (n/a - Unknown - ), Skin lesion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11448 | click or scan EU-EC-10009843730 |  | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11449 | click or scan EU-EC-10009843393 |  | 2021-08-31 | Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11450 | click or scan EU-EC-10009843344 | | 2021-08-31 | Healthcare Professional | EEA | 18-64 Years | Male | Diarrhoea (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11451 | click or scan EU-EC-10009842964 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11452 | click or scan EU-EC-10009842485 | | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic thrombosis (n/a - Unknown - ), Haemorrhage intracranial (1d - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Immune thrombocytopenia (n/a - Unknown - ), Portal vein thrombosis (n/a - Unknown - ), Pupil fixed (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11453 | click or scan EU-EC-10009841584 | | 2021-08-31 | Healthcare Professional | EEA | 18-64 Years | Female | Atelectasis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central nervous system necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Congestive hepatopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haematoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage subcutaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic ovarian cyst (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemothorax (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heparin-induced thrombocytopenia test positive (n/a - Unknown - ), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laryngeal haematoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pupils unequal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Right ventricular dilatation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vena cava thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 11454 | click or scan EU-EC-10009841416 | | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Encephalitis (4d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11455 | click or scan EU-EC-10009840612 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11456 | click or scan EU-EC-10009840591 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11457** | click or scan EU-EC-10009840584 | | 2021-08-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Painful respiration (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11458** | click or scan EU-EC-10009840221 | | 2021-08-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination site bruising (n/a - Fatal - **Results in Death**), Vaccination site haematoma (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **11459** | click or scan EU-EC-10009840216 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11460** | click or scan EU-EC-10009839875 | | 2021-08-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Anal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11461** | click or scan EU-EC-10009839627 | | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Unknown - Other Medically Important Condition), Discomfort (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage intracranial (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Venous haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| **11462** | click or scan EU-EC-10009839434 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11463** | click or scan EU-EC-10009839364 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11464** | click or scan EU-EC-10009839204 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11465** | click or scan EU-EC-10009839127 | | 2021-08-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (13d - Fatal - **Results in Death**), Cerebral haemorrhage (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (13d - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11466 | click or scan EU-EC-10009838614 | | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11467 | click or scan EU-EC-10009838595 | | 2021-08-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11468 | click or scan EU-EC-10009838584 | | 2021-08-31 | Non Healthcare Professional | Non EEA | Not Specified | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gastrointestinal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mobility decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11469 | click or scan EU-EC-10009837883 | | 2021-08-31 | Healthcare Professional | EEA | 65-85 Years | Male | Acute abdomen (16d - Fatal - **Results in Death**), Blood lactate dehydrogenase increased (16d - Fatal - **Results in Death**), Disorientation (16d - Fatal - **Results in Death**), Dyspnoea (16d - Fatal - **Results in Death**), Fibrin D dimer increased (16d - Fatal - **Results in Death**), Myocardial necrosis (16d - Fatal - **Results in Death**), Pulmonary embolism (16d - Fatal - **Results in Death**), Pyrexia (16d - Fatal - **Results in Death**), Sopor (16d - Fatal - **Results in Death**), Unresponsive to stimuli (16d - Fatal - **Results in Death**), Urine output decreased (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 11470 | click or scan EU-EC-10009837731 | | 2021-08-31 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (21d - Fatal - **Results in Death**), Dysstasia (21d - Fatal - **Results in Death**), Pyrexia (21d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 11471 | click or scan EU-EC-10009838106 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hospitalisation (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11472 | click or scan EU-EC-10009837219 | | 2021-08-30 | Healthcare Professional | EEA | 18-64 Years | Female | Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11473 | click or scan EU-EC-10009836052 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11474 | click or scan EU-EC-10009835994 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11475** | click or scan EU-EC-10009835964 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aspiration (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Hypotension (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11476** | click or scan EU-EC-10009835533 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemangioma (2d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11477** | click or scan EU-EC-10009835444 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Cerebral infarction (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11478** | click or scan EU-EC-10009835079 | | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Recovered/Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11479** | click or scan EU-EC-10009835000 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anuria (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Fall (n/a - Unknown - ), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11480** | click or scan EU-EC-10009834864 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11481** | click or scan EU-EC-10009834750 | | 2021-08-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Metastatic neoplasm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11482** | click or scan EU-EC-10009834548 | | 2021-08-30 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Disease recurrence (n/a - Unknown - ), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nausea (6d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11483** | click or scan EU-EC-10009834086 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **11484** | click or scan EU-EC-10009834059 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Infarction (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11485 | click or scan EU-EC-10009834053 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Burning sensation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Lid sulcus deepened (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Swelling face (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 11486 | click or scan EU-EC-10009833966 | | 2021-08-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Bed rest (n/a - Not Recovered/Not Resolved - ), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - ), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 11487 | click or scan EU-EC-10009833928 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11488 | click or scan EU-EC-10009833926 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11489 | click or scan EU-EC-10009833726 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11490 | click or scan EU-EC-10009833648 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11491 | click or scan EU-EC-10009833625 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11492 | click or scan EU-EC-10009833622 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11493 | click or scan EU-EC-10009833621 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11494 | click or scan EU-EC-10009833620 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11495 | click or scan EU-EC-10009833327 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11496 | click or scan EU-EC-10009833326 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11497 | click or scan EU-EC-10009833324 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11498 | click or scan EU-EC-10009833322 | | 2021-08-30 | Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11499 | click or scan EU-EC-10009833271 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11500 | click or scan EU-EC-10009833267 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11501 | click or scan EU-EC-10009833266 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11502 | click or scan EU-EC-10009833265 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11503 | click or scan EU-EC-10009833264 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11504 | click or scan EU-EC-10009833263 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11505 | click or scan EU-EC-10009833261 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Respiratory symptom (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S-Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11506** | click or scan EU-EC-10009833255 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11507** | click or scan EU-EC-10009833252 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11508** | click or scan EU-EC-10009833250 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11509** | click or scan EU-EC-10009833249 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Disabling), Pyrexia (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11510** | click or scan EU-EC-10009833248 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11511** | click or scan EU-EC-10009833243 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11512** | click or scan EU-EC-10009833242 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11513** | click or scan EU-EC-10009833241 |  | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11514** | click or scan EU-EC-10009833237 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pelvic pain (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11515** | click or scan EU-EC-10009833236 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11516** | click or scan EU-EC-10009833233 |  | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11517** | click or scan EU-EC-10009832518 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myelopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11518** | click or scan EU-EC-10009832503 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11519** | click or scan EU-EC-10009832351 | | 2021-08-30 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11520** | click or scan EU-EC-10009832296 | | 2021-08-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11521** | click or scan EU-EC-10009832256 | | 2021-08-30 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **11522** | click or scan EU-EC-10009832092 | | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11523** | click or scan EU-EC-10009832009 | | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11524** | click or scan EU-EC-10009831934 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11525** | click or scan EU-EC-10009831918 | | 2021-08-30 | Non Healthcare Professional | EEA | Not Specified | Male | Asthenia (n/a - Unknown - ), Blood pressure increased (n/a - Unknown - ), Body temperature increased (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11526** | click or scan EU-EC-10009831917 | | 2021-08-30 | Healthcare Professional | EEA | 18-64 Years | Female | Hepatic steatosis (n/a - Fatal - **Results in Death**), Toxic cardiomyopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11527** | click or scan EU-EC-10009831803 | | 2021-08-30 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11528** | click or scan EU-EC-10009831740 |  | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11529** | click or scan EU-EC-10009831494 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11530** | click or scan EU-EC-10009831429 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **11531** | click or scan EU-EC-10009830921 |  | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11532** | click or scan EU-EC-10009830907 |  | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**), Vaccination failure (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11533** | click or scan EU-EC-10009830665 |  | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Delirium (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11534** | click or scan EU-EC-10009830663 |  | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11535** | click or scan EU-EC-10009830655 |  | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Vertebral artery dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11536** | click or scan EU-EC-10009830649 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**), Hyperkalaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ileus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Small intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subileus (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11537** | click or scan EU-EC-10009830643 |  | 2021-08-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11538 | click or scan EU-EC-10009830514 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oral discharge (n/a - Not Recovered/Not Resolved - ), Salivary hypersecretion (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11539 | click or scan EU-EC-10009830507 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Choking (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11540 | click or scan EU-EC-10009830506 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematochezia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11541 | click or scan EU-EC-10009830502 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11542 | click or scan EU-EC-10009830347 | | 2021-08-30 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11543 | click or scan EU-EC-10009830002 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11544 | click or scan EU-EC-10009829837 | | 2021-08-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Gait disturbance (n/a - Unknown - Disabling, Other Medically Important Condition), General physical health deterioration (1d - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Respiratory tract infection (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2s - 1 {DF} - Intramuscular - More in ICSR]) |
| 11545 | click or scan EU-EC-10009829819 | | 2021-08-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11546 | click or scan EU-EC-10009829803 | | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (1h - Fatal - **Results in Death**), Loss of consciousness (1h - Fatal - **Results in Death**), Myocardial infarction (1h - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Subcutaneous]) |
| 11547 | click or scan EU-EC-10009829774 | | 2021-08-30 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (4d - Fatal - **Results in Death**), Sepsis (4d - Fatal - **Results in Death**), Urosepsis (4d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11548** | click or scan EU-EC-10009829615 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **11549** | click or scan EU-EC-10009829305 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **11550** | click or scan EU-EC-10009828515 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11551** | click or scan EU-EC-10009828512 | | 2021-08-30 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11552** | click or scan EU-EC-10009828511 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11553** | click or scan EU-EC-10009828510 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11554** | click or scan EU-EC-10009828507 | | 2021-08-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11555** | click or scan EU-EC-10009828506 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11556** | click or scan EU-EC-10009828505 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11557** | click or scan EU-EC-10009828504 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11558 | click or scan EU-EC-10009828483 |  | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11559 | click or scan EU-EC-10009828473 |  | 2021-08-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11560 | click or scan EU-EC-10009828471 |  | 2021-08-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11561 | click or scan EU-EC-10009828442 |  | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 11562 | click or scan EU-EC-10009828432 |  | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Female | Embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11563 | click or scan EU-EC-10009828371 |  | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (1wk - Fatal - **Results in Death**), Pneumonia (1wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11564 | click or scan EU-EC-10009828233 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Arthralgia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 11565 | click or scan EU-EC-10009828076 |  | 2021-08-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11566 | click or scan EU-EC-10009828032 |  | 2021-08-30 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (6wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11567 | click or scan EU-EC-10009827996 |  | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11568 | click or scan EU-EC-10009827626 |  | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Suicidal ideation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11569 | click or scan EU-EC-10009827594 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition), Lack of spontaneous speech (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11570 | click or scan EU-EC-10009827580 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Costochondritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11571 | click or scan EU-EC-10009827182 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11572 | click or scan EU-EC-10009826990 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac tamponade (1d - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [0d - n/a - n/a]) |
| 11573 | click or scan EU-EC-10009826360 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 11574 | click or scan EU-EC-10009826256 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening), Fall (n/a - Fatal - **Results in Death**, Life Threatening), Hypopnoea (n/a - Fatal - **Results in Death**, Life Threatening), Illness (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11575 | click or scan EU-EC-10009826184 | | 2021-08-30 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Anal sex (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ), Off label use (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11576 | click or scan EU-EC-10009825948 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cellulitis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11577 | click or scan EU-EC-10009825784 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11578 | click or scan EU-EC-10009825763 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11579** | click or scan EU-EC-10009825739 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Throat irritation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11580** | click or scan EU-EC-10009825532 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11581** | click or scan EU-EC-10009825529 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11582** | click or scan EU-EC-10009825524 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11583** | click or scan EU-EC-10009825504 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11584** | click or scan EU-EC-10009825499 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Upper airway obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11585** | click or scan EU-EC-10009825342 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11586** | click or scan EU-EC-10009825336 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dizziness (n/a - Recovered/Resolved - ), Dysphonia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11587** | click or scan EU-EC-10009825272 | | 2021-08-30 | Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pelvic mass (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11588 | click or scan EU-EC-10009824590 | | 2021-08-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 11589 | click or scan EU-EC-10009824496 | | 2021-08-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 11590 | click or scan EU-EC-10009824353 | | 2021-08-29 | Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Monoparesis (n/a - Fatal - **Results in Death**), Neck pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 11591 | click or scan EU-EC-10009823500 | | 2021-08-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (16h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 11592 | click or scan EU-EC-10009822600 | | 2021-08-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11593 | click or scan EU-EC-10009822209 | | 2021-08-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Crepitations (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Peripheral coldness (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11594 | click or scan EU-EC-10009822174 | | 2021-08-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Red man syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 11595 | click or scan EU-EC-10009822065 | | 2021-08-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11596 | click or scan EU-EC-10009821171 | | 2021-08-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11597 | click or scan EU-EC-10009821169 | | 2021-08-28 | Healthcare Professional | EEA | 18-64 Years | Male | Apraxia (30d - Fatal - **Results in Death**), Coma (30d - Fatal - **Results in Death**), Myocarditis (30d - Fatal - **Results in Death**), Septic shock (30d - Fatal - **Results in Death**), Ventricular dysfunction (30d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11598 | click or scan EU-EC-10009821145 |  | 2021-08-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cholestasis (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Dermatitis exfoliative generalised (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**), Subdural haematoma (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 11599 | click or scan EU-EC-10009820194 |  | 2021-08-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cough (2d - Fatal - **Results in Death**), Dyspnoea exertional (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| 11600 | click or scan EU-EC-10009819600 |  | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11601 | click or scan EU-EC-10009819491 |  | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11602 | click or scan EU-EC-10009819433 |  | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11603 | click or scan EU-EC-10009819090 |  | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11604 | click or scan EU-EC-10009819065 |  | 2021-08-27 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 11605 | click or scan EU-EC-10009818476 |  | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11606 | click or scan EU-EC-10009818301 |  | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11607 | click or scan EU-EC-10009818039 |  | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11608 | click or scan EU-EC-10009817896 |  | 2021-08-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11609** | click or scan EU-EC-10009817862 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Acute megakaryocytic leukaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - ), Contusion (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11610** | click or scan EU-EC-10009817708 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11611** | click or scan EU-EC-10009817703 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11612** | click or scan EU-EC-10009817548 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11613** | click or scan EU-EC-10009817453 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11614** | click or scan EU-EC-10009817423 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11615** | click or scan EU-EC-10009816935 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Physical deconditioning (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11616** | click or scan EU-EC-10009816815 | | 2021-08-27 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Eczema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Neoplasm progression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nervous system disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Neurological decompensation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Tumour rupture (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]), KEYTRUDA [PEMBROLIZUMAB] (S - Non-small cell lung cancer - Drug withdrawn - [189d - 200mg - n/a]), PEMETREXED [PEMETREXED, PEMETREXED DISODIUM HEMIPENTAHYDRATE] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]), [CISPLATIN] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]) |
| **11617** | click or scan EU-EC-10009816800 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11618 | click or scan EU-EC-10009816750 |  | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Medication error (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11619 | click or scan EU-EC-10009815943 |  | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11620 | click or scan EU-EC-10009815905 |  | 2021-08-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11621 | click or scan EU-EC-10009815898 |  | 2021-08-27 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11622 | click or scan EU-EC-10009815893 |  | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 11623 | click or scan EU-EC-10009815889 |  | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 11624 | click or scan EU-EC-10009815876 |  | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11625 | click or scan EU-EC-10009815846 |  | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 11626 | click or scan EU-EC-10009815712 |  | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Body temperature increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Cough (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Haemodynamic instability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11627 | click or scan EU-EC-10009815589 |  | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11628 | click or scan EU-EC-10009815253 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11629 | click or scan EU-EC-10009814964 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11630 | click or scan EU-EC-10009814941 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11631 | click or scan EU-EC-10009814779 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11632 | click or scan EU-EC-10009814698 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown - ), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Eye movement disorder (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Taste disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11633 | click or scan EU-EC-10009814682 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11634 | click or scan EU-EC-10009814680 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Choking (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Regurgitation (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11635 | click or scan EU-EC-10009814678 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - ), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11636 | click or scan EU-EC-10009814664 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11637 | click or scan EU-EC-10009814302 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11638 | click or scan EU-EC-10009813768 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11639 | click or scan EU-EC-10009812995 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11640 | click or scan EU-EC-10009812879 | | 2021-08-27 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiorenal syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11641 | click or scan EU-EC-10009811886 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11642 | click or scan EU-EC-10009811865 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11643 | click or scan EU-EC-10009811818 | | 2021-08-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11644 | click or scan EU-EC-10009810778 | | 2021-08-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11645 | click or scan EU-EC-10009810766 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11646 | click or scan EU-EC-10009810736 | | 2021-08-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11647 | click or scan EU-EC-10009810600 | | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary arterial stent insertion (n/a - Fatal - **Results in Death**), Percutaneous coronary intervention (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 11648 | click or scan EU-EC-10009809831 | | 2021-08-27 | Non Healthcare Professional | Non EEA | Not Specified | Female | Heart rate increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11649** | click or scan EU-EC-10009809813 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mood altered (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11650** | click or scan EU-EC-10009809667 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11651** | click or scan EU-EC-10009809633 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Febrile convulsion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11652** | click or scan EU-EC-10009809608 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11653** | click or scan EU-EC-10009809308 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11654** | click or scan EU-EC-10009808730 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**), Abdominal pain upper (n/a - Fatal - **Results in Death**), Anaemia (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11655** | click or scan EU-EC-10009807157 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Clavicle fracture (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Generalised oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11656** | click or scan EU-EC-10009806251 | | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11657** | click or scan EU-EC-10009806249 | | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (28d - Fatal - **Results in Death**), Cardiac failure (28d - Fatal - **Results in Death**), Headache (28d - Fatal - **Results in Death**), Pneumonitis aspiration (28d - Fatal - **Results in Death**), Vertigo (28d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11658** | click or scan EU-EC-10009806094 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic aneurysm (1d - Fatal - **Results in Death**), Aortic aneurysm rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis (1d - Fatal - **Results in Death**), Asthenia (1d - Fatal - **Results in Death**), Autopsy (1d - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Retroperitoneal haematoma (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11659** | click or scan EU-EC-10009807121 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Immediate post-injection reaction (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11660** | click or scan EU-EC-10009806858 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atypical pneumonia (94d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **11661** | click or scan EU-EC-10009806745 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell count increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11662** | click or scan EU-EC-10009806598 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11663** | click or scan EU-EC-10009806354 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11664** | click or scan EU-EC-10009806283 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11665** | click or scan EU-EC-10009805674 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11666** | click or scan EU-EC-10009805401 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Cerebrovascular disorder (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Head injury (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Skin laceration (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11667** | click or scan EU-EC-10009804810 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11668** | click or scan EU-EC-10009804592 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11669** | click or scan EU-EC-10009804534 | | 2021-08-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11670** | click or scan EU-EC-10009804510 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (3d - Fatal - **Results in Death**, Other Medically Important Condition), Death (3d - Fatal - **Results in Death**), Fall (3d - Fatal - **Results in Death**, Other Medically Important Condition), Restlessness (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11671** | click or scan EU-EC-10009804333 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**), Physical deconditioning (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **11672** | click or scan EU-EC-10009804100 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11673** | click or scan EU-EC-10009804042 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11674** | click or scan EU-EC-10009804020 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular]) |
| **11675** | click or scan EU-EC-10009803963 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11676** | click or scan EU-EC-10009803961 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11677** | click or scan EU-EC-10009803495 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11678** | click or scan EU-EC-10009803236 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11679** | click or scan EU-EC-10009803115 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Recovered/Resolved - ), Decreased appetite (n/a - Recovered/Resolved - ), Sleep disorder (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **11680** | click or scan EU-EC-10009802111 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |
| **11681** | click or scan EU-EC-10009802087 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (25d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - 1 {DF} - Intramuscular]) |
| **11682** | click or scan EU-EC-10009802076 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11683** | click or scan EU-EC-10009802054 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11684** | click or scan EU-EC-10009802051 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11685** | click or scan EU-EC-10009802039 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11686** | click or scan EU-EC-10009802037 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Female | Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation), Body temperature increased (2d - Recovered/Resolved - ), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (2d - Recovered/Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [DROSPIRENONE, ETHINYLESTRADIOL] (S - Contraception - Not applicable - [n/a - n/a - Oral]) |
| **11687** | click or scan EU-EC-10009802027 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Diarrhoea (3d - Recovered/Resolved - ), Pruritus (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11688** | click or scan EU-EC-10009801984 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11689 | click or scan EU-EC-10009801969 |  | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11690 | click or scan EU-EC-10009801946 |  | 2021-08-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 11691 | click or scan EU-EC-10009801880 |  | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11692 | click or scan EU-EC-10009801855 |  | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 11693 | click or scan EU-EC-10009801703 |  | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 11694 | click or scan EU-EC-10009801566 |  | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 11695 | click or scan EU-EC-10009801298 |  | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11696 | click or scan EU-EC-10009801114 |  | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebellar infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle rigidity (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11697 | click or scan EU-EC-10009801082 |  | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11698 | click or scan EU-EC-10009800756 |  | 2021-08-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11699 | click or scan EU-EC-10009800753 |  | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11700** | click or scan EU-EC-10009800748 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11701** | click or scan EU-EC-10009800738 | | 2021-08-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Gait disturbance (n/a - Unknown - Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11702** | click or scan EU-EC-10009800710 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11703** | click or scan EU-EC-10009799743 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11704** | click or scan EU-EC-10009798983 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anaemia (25d - Fatal - **Results in Death**), Blood urine present (25d - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Renal impairment (25d - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11705** | click or scan EU-EC-10009798961 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dysphagia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Myasthenia gravis (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **11706** | click or scan EU-EC-10009798758 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Mydriasis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **11707** | click or scan EU-EC-10009798622 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11708** | click or scan EU-EC-10009797886 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11709** | click or scan EU-EC-10009797552 | | 2021-08-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11710 | click or scan EU-EC-10009797079 |  | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (8d - Unknown - Caused/Prolonged Hospitalisation), Death (8d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic encephalopathy (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Toxicity to various agents (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Viral infection (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11711 | click or scan EU-EC-10009796694 |  | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11712 | click or scan EU-EC-10009796551 |  | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Benign prostatic hyperplasia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothyroidism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive airway pressure therapy (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11713 | click or scan EU-EC-10009796018 |  | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11714 | click or scan EU-EC-10009795702 |  | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthropod bite (n/a - Unknown - Caused/Prolonged Hospitalisation), Delirium (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Escherichia sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Severe fever with thrombocytopenia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11715 | click or scan EU-EC-10009795255 |  | 2021-08-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11716 | click or scan EU-EC-10009795224 |  | 2021-08-26 | Non Healthcare Professional | EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11717 | click or scan EU-EC-10009795191 |  | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11718 | click or scan EU-EC-10009795112 |  | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11719 | click or scan EU-EC-10009794752 |  | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | Terminal state (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 11720 | click or scan EU-EC-10009794486 |  | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Castleman's disease (89d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 11721 | click or scan EU-EC-10009793199 |  | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11722 | click or scan EU-EC-10009791824 |  | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Computerised tomogram abdomen (n/a - Fatal - **Results in Death**), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Intestinal resection (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Surgery (n/a - Fatal - **Results in Death**), Visceral venous thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11723 | click or scan EU-EC-10009791785 |  | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Regurgitation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11724 | click or scan EU-EC-10009791050 |  | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11725 | click or scan EU-EC-10009790845 |  | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11726 | click or scan EU-EC-10009790631 |  | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 11727 | click or scan EU-EC-10009790617 |  | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Female | Pancytopenia (n/a - Fatal - **Results in Death**), Toxic epidermal necrolysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (S - Rheumatoid arthritis - n/a - [n/a - 25mg - Subcutaneous]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11728 | click or scan EU-EC-10009790596 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]) |
| 11729 | click or scan EU-EC-10009790530 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anxiety (57d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (57d - Fatal - **Results in Death**), Impaired driving ability (57d - Fatal - **Results in Death**), Malaise (57d - Fatal - **Results in Death**), Night sweats (57d - Fatal - **Results in Death**), Pain (57d - Fatal - **Results in Death**), Sarcoma (57d - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell count increased (57d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11730 | click or scan EU-EC-10009790359 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11731 | click or scan EU-EC-10009790215 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (31d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11732 | click or scan EU-EC-10009790123 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Unknown - ), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11733 | click or scan EU-EC-10009789999 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agonal respiration (1d - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (1d - Fatal - **Results in Death**), Coronary artery thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**), Myocardial rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11734 | click or scan EU-EC-10009789930 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11735 | click or scan EU-EC-10009789927 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Hypotension (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11736 | click or scan EU-EC-10009789849 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11737 | click or scan EU-EC-10009789816 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 11738 | click or scan EU-EC-10009789590 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cellulitis (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11739 | click or scan EU-EC-10009789431 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11740 | click or scan EU-EC-10009789136 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11741 | click or scan EU-EC-10009788937 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular]) |
| 11742 | click or scan EU-EC-10009788927 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1{DF} - Intramuscular]) |
| 11743 | click or scan EU-EC-10009788724 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2[arb'U] - n/a]) |
| 11744 | click or scan EU-EC-10009788694 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11745 | click or scan EU-EC-10009788594 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11746 | click or scan EU-EC-10009788469 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11747 | click or scan EU-EC-10009788453 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11748 | click or scan EU-EC-10009788435 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eating disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11749 | click or scan EU-EC-10009788275 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (8d - Fatal - **Results in Death**), Cough (8d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Recovered/Resolved - ), Myalgia (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11750 | click or scan EU-EC-10009788145 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Hepatic steatosis (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11751 | click or scan EU-EC-10009788104 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autoimmune haemolytic anaemia (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Campylobacter gastroenteritis (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Castleman's disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11752 | click or scan EU-EC-10009787952 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 11753 | click or scan EU-EC-10009787917 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11754 | click or scan EU-EC-10009787862 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Herpes zoster (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11755 | click or scan EU-EC-10009787788 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11756 | click or scan EU-EC-10009787761 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (1mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (1mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (1mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11757 | click or scan EU-EC-10009787712 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - ), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 11758 | click or scan EU-EC-10009787263 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dementia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 11759 | click or scan EU-EC-10009787246 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Monoplegia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11760 | click or scan EU-EC-10009787186 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Malaise (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11761 | click or scan EU-EC-10009787023 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anticoagulant therapy (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal infarct (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11762 | click or scan EU-EC-10009786926 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11763 | click or scan EU-EC-10009786743 | | 2021-08-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Breast cancer recurrent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11764 | click or scan EU-EC-10009786728 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11765 | click or scan EU-EC-10009786705 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ), Hypertension (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumoconiosis (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11766 | click or scan EU-EC-10009786384 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Female | Malignant hypertension (n/a - Fatal - **Results in Death**), Posterior reversible encephalopathy syndrome (n/a - Fatal - **Results in Death**), Status epilepticus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11767 | click or scan EU-EC-10009786381 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11768 | click or scan EU-EC-10009786369 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (13d - Fatal - **Results in Death**), Vaccination failure (13d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 11769 | click or scan EU-EC-10009786284 | | 2021-08-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11770 | click or scan EU-EC-10009786152 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Lymphadenopathy (175d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoedema (175d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 11771 | click or scan EU-EC-10009786139 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11772 | click or scan EU-EC-10009786096 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11773 | click or scan EU-EC-10009786072 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apallic syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11774 | click or scan EU-EC-10009786055 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 11775 | click or scan EU-EC-10009785933 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11776 | click or scan EU-EC-10009785790 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11777 | click or scan EU-EC-10009785666 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Angina pectoris (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11778** | click or scan EU-EC-10009785641 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11779** | click or scan EU-EC-10009785640 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pain in extremity (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11780** | click or scan EU-EC-10009785636 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]) |
| **11781** | click or scan EU-EC-10009785579 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Sudden cardiac death (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11782** | click or scan EU-EC-10009785427 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11783** | click or scan EU-EC-10009785373 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11784** | click or scan EU-EC-10009785223 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (17d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11785** | click or scan EU-EC-10009784912 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11786** | click or scan EU-EC-10009784881 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11787** | click or scan EU-EC-10009784842 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11788** | click or scan EU-EC-10009784840 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11789** | click or scan EU-EC-10009784739 | | 2021-08-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Obstructive pancreatitis (10d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11790** | click or scan EU-EC-10009784732 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **11791** | click or scan EU-EC-10009784720 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [41d - 2 {DF} - Intramuscular]) |
| **11792** | click or scan EU-EC-10009784710 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bladder catheterisation (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cerebral small vessel ischaemic disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic sinusitis (n/a - Fatal - **Results in Death**), Coma scale (n/a - Fatal - **Results in Death**), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Endotracheal intubation (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11793** | click or scan EU-EC-10009784677 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [19d - 1 {DF} - Intramuscular]) |
| **11794** | click or scan EU-EC-10009784676 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11795** | click or scan EU-EC-10009784672 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dehydration (n/a - Unknown - ), Face crushing (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11796** | click or scan EU-EC-10009784460 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (2d - Fatal - **Results in Death**), Abdominal pain upper (2d - Fatal - **Results in Death**), Back pain (2d - Fatal - **Results in Death**), Myocarditis (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11797** | click or scan EU-EC-10009784162 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11798 | click or scan EU-EC-10009784026 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 11799 | click or scan EU-EC-10009783960 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11800 | click or scan EU-EC-10009783817 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11801 | click or scan EU-EC-10009783466 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Back pain (n/a - Not Recovered/Not Resolved - ), Burning sensation (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Gait inability (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Memory impairment (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Thinking abnormal (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 11802 | click or scan EU-EC-10009783422 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 11803 | click or scan EU-EC-10009783401 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 11804 | click or scan EU-EC-10009783373 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 11805 | click or scan EU-EC-10009783298 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (3d - Fatal - **Results in Death**), Death (3d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (3d - Fatal - **Results in Death**), Life support (3d - Fatal - **Results in Death**), Organ donor (3d - Fatal - **Results in Death**), Syncope (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11806 | click or scan EU-EC-10009783075 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11807 | click or scan EU-EC-10009782854 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11808** | click or scan EU-EC-10009782825 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Intestinal haemorrhage (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11809** | click or scan EU-EC-10009782775 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11810** | click or scan EU-EC-10009782654 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Product administered at inappropriate site (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| **11811** | click or scan EU-EC-10009782451 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11812** | click or scan EU-EC-10009782302 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event (n/a - Fatal - **Results in Death**), Headache (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **11813** | click or scan EU-EC-10009782236 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (1mo - Fatal - **Results in Death**), Cough (1mo - Fatal - **Results in Death**), Dehydration (57d - Fatal - **Results in Death**), Depressed level of consciousness (1mo - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (28d - Fatal - **Results in Death**), Feeling abnormal (1mo - Fatal - **Results in Death**), Feeling hot (1mo - Fatal - **Results in Death**), Insomnia (1mo - Fatal - **Results in Death**), Pyrexia (1mo - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11814** | click or scan EU-EC-10009782199 | | 2021-08-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (3070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1309min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (3070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (3070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11815** | click or scan EU-EC-10009782139 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11816** | click or scan EU-EC-10009782080 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11817** | click or scan EU-EC-10009781677 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dermatitis exfoliative generalised (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Psoriasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **11818** | click or scan EU-EC-10009781366 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Congestive cardiomyopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11819 | click or scan EU-EC-10009780950 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 11820 | click or scan EU-EC-10009780947 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (6d - Fatal - **Results in Death**), Death (6d - Fatal - **Results in Death**), Oedema peripheral (6d - Fatal - **Results in Death**), Pulmonary embolism (6d - Fatal - **Results in Death**), Respiratory failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 11821 | click or scan EU-EC-10009780925 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral ischaemia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Superficial vein thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 11822 | click or scan EU-EC-10009780909 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Male | Septic shock (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11823 | click or scan EU-EC-10009780317 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11824 | click or scan EU-EC-10009780218 | | 2021-08-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11825 | click or scan EU-EC-10009780133 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11826 | click or scan EU-EC-10009780128 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cor pulmonale (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 11827 | click or scan EU-EC-10009780117 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal haemorrhage (0d - Fatal - **Results in Death**), Hypotension (0d - Unknown - ), Hypothermia (0d - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 11828 | click or scan EU-EC-10009780102 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11829 | click or scan EU-EC-10009780096 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11830 | click or scan EU-EC-10009780084 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epistaxis (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11831 | click or scan EU-EC-10009780061 | | 2021-08-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (32d - Fatal - **Results in Death**, Life Threatening), Dementia (32d - Fatal - **Results in Death**, Life Threatening), Urinary incontinence (32d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 11832 | click or scan EU-EC-10009778826 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11833 | click or scan EU-EC-10009778575 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 11834 | click or scan EU-EC-10009778569 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11835 | click or scan EU-EC-10009778017 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| 11836 | click or scan EU-EC-10009777955 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11837 | click or scan EU-EC-10009777624 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11838 | click or scan EU-EC-10009775660 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11839 | click or scan EU-EC-10009775283 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11840** | click or scan EU-EC-10009775257 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **11841** | click or scan EU-EC-10009775108 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11842** | click or scan EU-EC-10009775094 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **11843** | click or scan EU-EC-10009775027 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [1d - .3mL - Intramuscular]) |
| **11844** | click or scan EU-EC-10009774995 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **11845** | click or scan EU-EC-10009774982 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11846** | click or scan EU-EC-10009774981 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**), Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11847** | click or scan<br>EU-EC-10009774846 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ammonia increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anion gap decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood calcium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood chloride normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood magnesium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carbon dioxide normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell haemoglobin concentration normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell haemoglobin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell volume normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oesophageal variceal ligation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oesophageal varices haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oesophagogastroduodenoscopy abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11848** | click or scan<br>EU-EC-10009774768 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Antibody test positive (n/a - Unknown - ), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Catatonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunology test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Sinus disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11849** | click or scan<br>EU-EC-10009774435 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11850 | click or scan EU-EC-10009774366 | | 2021-08-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11851 | click or scan EU-EC-10009774321 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11852 | click or scan EU-EC-10009774216 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood creatine phosphokinase increased (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Fatal - **Results in Death**), Oliguria (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 11853 | click or scan EU-EC-10009774170 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11854 | click or scan EU-EC-10009774122 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11855 | click or scan EU-EC-10009774013 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 11856 | click or scan EU-EC-10009773939 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11857 | click or scan EU-EC-10009773870 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11858 | click or scan EU-EC-10009773810 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Acute abdomen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood lactate dehydrogenase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sopor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urine output decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]), LEVOFLOXACIN [LEVOFLOXACIN] (S - Dyspnoea - Not applicable - [n/a - 500mg - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11859** | click or scan EU-EC-10009773670 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11860** | click or scan EU-EC-10009773649 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **11861** | click or scan EU-EC-10009773280 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Transverse sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11862** | click or scan EU-EC-10009772306 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Lethargy (n/a - Unknown - ), Peripheral coldness (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11863** | click or scan EU-EC-10009771125 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11864** | click or scan EU-EC-10009771120 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11865** | click or scan EU-EC-10009771114 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11866** | click or scan EU-EC-10009771112 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Toothache (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11867** | click or scan EU-EC-10009771110 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11868** | click or scan EU-EC-10009771106 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11869 | click or scan EU-EC-10009771105 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11870 | click or scan EU-EC-10009771100 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11871 | click or scan EU-EC-10009771085 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Erythema (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11872 | click or scan EU-EC-10009771023 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11873 | click or scan EU-EC-10009770720 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Concomitant disease aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemodynamic instability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Livedo reticularis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 11874 | click or scan EU-EC-10009770700 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**), Blood pressure immeasurable (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11875 | click or scan EU-EC-10009770629 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11876 | click or scan EU-EC-10009770510 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hospitalisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Oral candidiasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Peroneal nerve palsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Rales (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11877 | click or scan EU-EC-10009770467 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [28d - .5mL - Intramuscular]) |
| 11878 | click or scan EU-EC-10009769729 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Adrenal insufficiency (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Polymyositis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Procalcitonin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11879 | click or scan EU-EC-10009769701 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 11880 | click or scan EU-EC-10009769554 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [2s - .5mL - Intramuscular]) |
| 11881 | click or scan EU-EC-10009768721 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary congestion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 11882 | click or scan EU-EC-10009768471 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Gastrointestinal haemorrhage (74d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11883 | click or scan EU-EC-10009768331 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11884 | click or scan EU-EC-10009768281 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11885 | click or scan EU-EC-10009767522 | | 2021-08-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11886 | click or scan EU-EC-10009766547 | | 2021-08-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 11887 | click or scan EU-EC-10009765785 | | 2021-08-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11888 | click or scan EU-EC-10009765259 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11889 | click or scan EU-EC-10009765227 | | 2021-08-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (15d - Fatal - **Results in Death**), Drug ineffective (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 11890 | click or scan EU-EC-10009765226 | | 2021-08-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 11891 | click or scan EU-EC-10009764904 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11892 | click or scan EU-EC-10009764414 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Demyelination (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11893 | click or scan EU-EC-10009764374 | | 2021-08-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 11894 | click or scan EU-EC-10009764177 | | 2021-08-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Diplegia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Paraesthesia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 11895 | click or scan EU-EC-10009764098 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal function test abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11896** | click or scan EU-EC-10009763655 |  | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**), Hyperthermia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **11897** | click or scan EU-EC-10009762738 |  | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pancreatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11898** | click or scan EU-EC-10009762734 |  | 2021-08-23 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Sinus disorder (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11899** | click or scan EU-EC-10009762469 |  | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11900** | click or scan EU-EC-10009762254 |  | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11901** | click or scan EU-EC-10009762198 |  | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| **11902** | click or scan EU-EC-10009761377 |  | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [85d - 2{DF} - Intramuscular]) |
| **11903** | click or scan EU-EC-10009761334 |  | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **11904** | click or scan EU-EC-10009761323 |  | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| **11905** | click or scan EU-EC-10009761309 |  | 2021-08-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11906 | click or scan EU-EC-10009761300 | | 2021-08-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 11907 | click or scan EU-EC-10009761246 | | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) |
| 11908 | click or scan EU-EC-10009761245 | | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11909 | click or scan EU-EC-10009761082 | | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 11910 | click or scan EU-EC-10009761058 | | 2021-08-23 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| 11911 | click or scan EU-EC-10009761049 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac valve disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11912 | click or scan EU-EC-10009760937 | | 2021-08-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - Other Medically Important Condition), Disorientation (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 11913 | click or scan EU-EC-10009760466 | | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11914 | click or scan EU-EC-10009760425 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Limb discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Off label use (n/a - Unknown - ), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | ZOLEDRONIC ACID [ZOLEDRONIC ACID] (S - Osteoporosis prophylaxis - Not applicable - [n/a - 5mg - Intravenous drip]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11915 | click or scan EU-EC-10009760382 | | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11916 | click or scan EU-EC-10009759722 | | 2021-08-23 | Healthcare Professional | Non EEA | Not Specified | Male | Body temperature decreased (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 11917 | click or scan EU-EC-10009759070 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11918 | click or scan EU-EC-10009758925 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11919 | click or scan EU-EC-10009758536 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11920 | click or scan EU-EC-10009758529 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Autonomic neuropathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11921 | click or scan EU-EC-10009758525 | | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11922 | click or scan EU-EC-10009757741 | | 2021-08-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11923 | click or scan EU-EC-10009757735 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Throat irritation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 11924 | click or scan EU-EC-10009756733 | | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11925 | click or scan EU-EC-10009756728 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic cardiomyopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11926 | click or scan EU-EC-10009756724 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11927 | click or scan EU-EC-10009756713 | | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 11928 | click or scan EU-EC-10009756612 | | 2021-08-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Unknown - ), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Nephrolithiasis (n/a - Unknown - Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 11929 | click or scan EU-EC-10009754767 | | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| 11930 | click or scan EU-EC-10009754766 | | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| 11931 | click or scan EU-EC-10009753762 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (4d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 11932 | click or scan EU-EC-10009753673 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Drug ineffective (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subdural haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]), LEVETIRACETAM [LEVETIRACETAM] (S - Partial seizures - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]), [HEPARIN, HEPARIN SODIUM] (S - Thrombosis - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]), [IMMUNGLOBULIN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 11933 | click or scan EU-EC-10009753574 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (14d - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Intracranial pressure increased (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11934 | click or scan EU-EC-10009753556 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Coronary artery dissection (7d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Joint swelling (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11935 | click or scan EU-EC-10009753537 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11936 | click or scan EU-EC-10009753533 | | 2021-08-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anti-neutrophil cytoplasmic antibody positive vasculitis (53d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary vasculitis (53d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal vasculitis (53d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (53d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11937 | click or scan EU-EC-10009753258 | | 2021-08-21 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 11938 | click or scan EU-EC-10009753072 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Chronic obstructive pulmonary disease (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Heart rate increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hypertension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pulmonary oedema (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 11939 | click or scan EU-EC-10009753069 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11940 | click or scan EU-EC-10009753068 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 11941 | click or scan EU-EC-10009753067 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Basilar artery thrombosis (6d - Fatal - **Results in Death**), Brain stem stroke (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**), Visual impairment (n/a - Not Recovered/Not Resolved - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11942 | click or scan EU-EC-10009753066 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pancreatic cyst (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 11943 | click or scan EU-EC-10009753065 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11944** | click or scan EU-EC-10009753056 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cardiac disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cerebral disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Groin pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11945** | click or scan EU-EC-10009753053 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Ear infection (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Neck pain (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11946** | click or scan EU-EC-10009753048 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anisocytosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Polychromasia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11947** | click or scan EU-EC-10009753045 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Body temperature decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersomnia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11948** | click or scan EU-EC-10009751586 | | 2021-08-21 | Healthcare Professional | EEA | 65-85 Years | Female | Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Musculoskeletal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **11949** | click or scan EU-EC-10009751330 | | 2021-08-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Blood albumin decreased (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **11950** | click or scan EU-EC-10009750890 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11951** | click or scan EU-EC-10009750320 | | 2021-08-20 | Healthcare Professional | Non EEA | Not Specified | Female | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **11952** | click or scan EU-EC-10009750319 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **11953** | click or scan EU-EC-10009750078 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (3d - Fatal - **Results in Death**, Life Threatening), Intestinal ischaemia (3d - Fatal - **Results in Death**, Life Threatening), Vaccination failure (3d - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11954** | click or scan EU-EC-10009749750 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**), Depression (n/a - Not Recovered/Not Resolved - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Incomplete course of vaccination (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Not applicable - [n/a - n/a - Intramuscular]) |
| **11955** | click or scan EU-EC-10009749464 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral mass effect (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11956** | click or scan EU-EC-10009749285 | | 2021-08-20 | Healthcare Professional | EEA | More than 85 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11957** | click or scan EU-EC-10009749190 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphonia (2d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Oropharyngeal pain (2d - Fatal - **Results in Death**), Pollakiuria (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **11958** | click or scan EU-EC-10009748956 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11959** | click or scan EU-EC-10009748664 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **11960** | click or scan EU-EC-10009748655 | | 2021-08-20 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (18d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **11961** | click or scan EU-EC-10009748643 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11962 | click or scan EU-EC-10009748629 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cranial nerve disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11963 | click or scan EU-EC-10009748561 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11964 | click or scan EU-EC-10009748558 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11965 | click or scan EU-EC-10009748544 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11966 | click or scan EU-EC-10009748182 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Blood pressure fluctuation (n/a - Unknown - ), Chills (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**), Tremor (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11967 | click or scan EU-EC-10009748096 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 11968 | click or scan EU-EC-10009748041 | | 2021-08-20 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11969 | click or scan EU-EC-10009748040 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11970 | click or scan EU-EC-10009748039 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 11971 | click or scan EU-EC-10009748021 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Female | Pancreatic carcinoma (77d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **11972** | click or scan EU-EC-10009748004 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **11973** | click or scan EU-EC-10009747981 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Vaccination site erythema (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11974** | click or scan EU-EC-10009747959 | | 2021-08-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **11975** | click or scan EU-EC-10009747951 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aphthous ulcer (3d - Fatal - **Results in Death**), Pain in extremity (3d - Fatal - **Results in Death**), Rash (3d - Fatal - **Results in Death**), Tongue oedema (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INDAPAMIDE, PERINDOPRIL ARGININE, PERINDOPRIL TERT-BUTYLAMINE, INDAPAMIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [NEBIVOLOL] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]) |
| **11976** | click or scan EU-EC-10009747921 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11977** | click or scan EU-EC-10009747918 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Irritability (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **11978** | click or scan EU-EC-10009747326 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic shock (5h - Fatal - **Results in Death**), Cardiac failure acute (5h - Fatal - **Results in Death**), Pancytopenia (5h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1[arb'U] - n/a]) |
| **11979** | click or scan EU-EC-10009747228 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 11980 | click or scan EU-EC-10009746965 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary artery occlusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11981 | click or scan EU-EC-10009746928 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abscess (n/a - Unknown - ), Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Unknown - Other Medically Important Condition), Febrile convulsion (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Toxic shock syndrome (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 11982 | click or scan EU-EC-10009746683 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 11983 | click or scan EU-EC-10009746659 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Heat illness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| 11984 | click or scan EU-EC-10009746385 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1 d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11985 | click or scan EU-EC-10009746205 | | 2021-08-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| 11986 | click or scan EU-EC-10009745976 | | 2021-08-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11987 | click or scan EU-EC-10009745913 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11988 | click or scan EU-EC-10009745912 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pain (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 11989 | click or scan EU-EC-10009745030 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Female | Condition aggravated (34 d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rash (34 d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [5 s - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 11990 | click or scan EU-EC-10009744951 |  | 2021-08-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemoptysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11991 | click or scan EU-EC-10009744624 |  | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 11992 | click or scan EU-EC-10009744611 |  | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 11993 | click or scan EU-EC-10009744425 |  | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 11994 | click or scan EU-EC-10009744113 |  | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Blindness (n/a - Unknown - Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 11995 | click or scan EU-EC-10009744064 |  | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 11996 | click or scan EU-EC-10009743750 |  | 2021-08-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Endocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 11997 | click or scan EU-EC-10009743414 |  | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Unknown - ), Local reaction (n/a - Unknown - ), Toxic shock syndrome (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11998 | click or scan EU-EC-10009743392 |  | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 11999 | click or scan EU-EC-10009743388 |  | 2021-08-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12000 | click or scan EU-EC-10009743385 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12001 | click or scan EU-EC-10009743060 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Cardiogenic shock (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Hypersomnia (n/a - Unknown - ), Illness (n/a - Unknown - ), Incoherent (n/a - Unknown - ), Malaise (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12002 | click or scan EU-EC-10009742891 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bone pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Surgery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12003 | click or scan EU-EC-10009742890 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 12004 | click or scan EU-EC-10009742844 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12005 | click or scan EU-EC-10009742477 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure increased (0d - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Injection site pain (2d - Recovered/Resolved - ), Syncope (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12006 | click or scan EU-EC-10009742330 | | 2021-08-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (1d - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coordination abnormal (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - ), Paralysis (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Thrombosis (1d - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12007 | click or scan EU-EC-10009742284 | | 2021-08-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12008 | click or scan EU-EC-10009742281 | | 2021-08-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12009 | click or scan EU-EC-10009742278 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12010** | click or scan EU-EC-10009742067 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **12011** | click or scan EU-EC-10009741976 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12012** | click or scan EU-EC-10009741302 | | 2021-08-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12013** | click or scan EU-EC-10009740948 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12014** | click or scan EU-EC-10009740944 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ), Embolic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12015** | click or scan EU-EC-10009740912 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **12016** | click or scan EU-EC-10009740770 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **12017** | click or scan EU-EC-10009739831 | | 2021-08-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Language disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **12018** | click or scan EU-EC-10009739337 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12019** | click or scan EU-EC-10009739328 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (9d - Fatal - **Results in Death**), Cough (9d - Unknown - ), Pyrexia (9d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12020** | click or scan EU-EC-10009739319 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (34d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12021 | click or scan EU-EC-10009739316 |  | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (10d - Fatal - **Results in Death**), Cough (10d - Unknown - ), Dyspnoea (10d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12022 | click or scan EU-EC-10009739313 |  | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12023 | click or scan EU-EC-10009739115 |  | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arterial thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visceral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 12024 | click or scan EU-EC-10009739013 |  | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure abnormal (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Body temperature increased (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Irritability (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal injury (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary retention (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12025 | click or scan EU-EC-10009739007 |  | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Leukopenia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12026 | click or scan EU-EC-10009738765 |  | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12027 | click or scan EU-EC-10009738583 |  | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12028 | click or scan EU-EC-10009738273 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12029 | click or scan EU-EC-10009738272 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Tachypnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12030 | click or scan EU-EC-10009738262 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12031 | click or scan EU-EC-10009738214 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Not Recovered/Not Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neck pain (n/a - Not Recovered/Not Resolved - ), Pulmonary thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12032 | click or scan EU-EC-10009738204 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12033 | click or scan EU-EC-10009738194 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypopnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12034 | click or scan EU-EC-10009738192 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12035 | click or scan EU-EC-10009737693 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12036 | click or scan EU-EC-10009737613 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (19d - Fatal - **Results in Death**), Pneumonia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12037 | click or scan EU-EC-10009737388 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12038 | click or scan EU-EC-10009736638 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Computerised tomogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12039 | click or scan EU-EC-10009735183 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Sudden cardiac death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12040 | click or scan EU-EC-10009734866 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [36d - 1 {DF} - Intramuscular]) |
| 12041 | click or scan EU-EC-10009734848 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 12042 | click or scan EU-EC-10009734847 | | 2021-08-19 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Confusional state (6d - Fatal - **Results in Death**), Interstitial lung disease (6d - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [37d - 1 {DF} - Intramuscular]) |
| 12043 | click or scan EU-EC-10009734793 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12044 | click or scan EU-EC-10009734769 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), RITUXIMAB [RITUXIMAB] (S - Muscular weakness - Dose not changed - [n/a - 1 {DF} - Intravenous (not otherwise specified)]) |
| 12045 | click or scan EU-EC-10009734643 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12046 | click or scan EU-EC-10009734505 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12047 | click or scan EU-EC-10009734500 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Male | Atrial fibrillation (3d - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Metabolic acidosis (3d - Fatal - **Results in Death**), Shock (3d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12048 | click or scan EU-EC-10009734494 |  | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary fibrosis (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12049 | click or scan EU-EC-10009734492 |  | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12050 | click or scan EU-EC-10009734355 |  | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchospasm (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic lesion (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary mass (n/a - Unknown - Other Medically Important Condition), Renal function test abnormal (n/a - Unknown - ), Wheezing (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12051 | click or scan EU-EC-10009734322 |  | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (n/a - Unknown - ), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Blood alkaline phosphatase decreased (n/a - Unknown - ), Blood creatinine decreased (n/a - Unknown - ), Blood thyroid stimulating hormone decreased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Cardiothoracic ratio increased (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Lymphocyte count decreased (n/a - Unknown - ), Malaise (n/a - Unknown - ), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Mean cell volume decreased (n/a - Unknown - ), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Orthopnoea (n/a - Unknown - ), Pallor (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Reticulocyte count decreased (n/a - Unknown - ), Ventricular failure (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12052 | click or scan EU-EC-10009734258 |  | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Unknown - Caused/Prolonged Hospitalisation), Glycosylated haemoglobin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sputum purulent (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12053 | click or scan EU-EC-10009734253 |  | 2021-08-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12054 | click or scan EU-EC-10009733462 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eczema (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malignant neoplasm progression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nervous system disorder (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological decompensation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), KEYTRUDA [PEMBROLIZUMAB] (S - Non-small cell lung cancer - Drug withdrawn - [n/a - 200mg - n/a]), KEYTRUDA [PEMBROLIZUMAB] (S - n/a - Drug withdrawn - [166d - 200mg - n/a]), PEMETREXED [PEMETREXED, PEMETREXED DISODIUM HEMIPENTAHYDRATE] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]), [CISPLATIN] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]) |
| 12055 | click or scan EU-EC-10009733313 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12056 | click or scan EU-EC-10009733294 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12057 | click or scan EU-EC-10009732735 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12058 | click or scan EU-EC-10009732159 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Respiratory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12059 | click or scan EU-EC-10009731417 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12060 | click or scan EU-EC-10009730781 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Large intestine perforation (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12061 | click or scan EU-EC-10009730630 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12062** | click or scan EU-EC-10009730511 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12063** | click or scan EU-EC-10009730130 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (1d - Fatal - **Results in Death**), Stomatitis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **12064** | click or scan EU-EC-10009730013 | | 2021-08-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Brain death (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Endocarditis (n/a - Fatal - **Results in Death**), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Mutism (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pupils unequal (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12065** | click or scan EU-EC-10009729913 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (1d - Fatal - **Results in Death**), Carditis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12066** | click or scan EU-EC-10009729332 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (31d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **12067** | click or scan EU-EC-10009729253 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12068** | click or scan EU-EC-10009728763 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **12069** | click or scan EU-EC-10009728661 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12070** | click or scan EU-EC-10009728625 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukaemia (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Walking aid user (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12071 | click or scan EU-EC-10009728565 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immediate post-injection reaction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12072 | click or scan EU-EC-10009728420 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Rib fracture (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12073 | click or scan EU-EC-10009728123 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 12074 | click or scan EU-EC-10009727998 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12075 | click or scan EU-EC-10009727523 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute hepatic failure (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperferritinaemia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia legionella (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12076 | click or scan EU-EC-10009727488 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Male | Hyperpyrexia (10d - Fatal - **Results in Death**), Respiratory failure (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 12077 | click or scan EU-EC-10009727473 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Infection (n/a - Fatal - **Results in Death**), Respiratory fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 12078 | click or scan EU-EC-10009727433 | | 2021-08-19 | Healthcare Professional | EEA | More than 85 Years | Female | Peripheral ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12079** | click or scan EU-EC-10009727378 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **12080** | click or scan EU-EC-10009727372 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhagic pneumonia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **12081** | click or scan EU-EC-10009727362 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12082** | click or scan EU-EC-10009727358 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **12083** | click or scan EU-EC-10009727355 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **12084** | click or scan EU-EC-10009727351 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac disorder (95d - Fatal - **Results in Death**), Pulmonary embolism (95d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **12085** | click or scan EU-EC-10009727348 | | 2021-08-19 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **12086** | click or scan EU-EC-10009727344 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **12087** | click or scan EU-EC-10009727316 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Female | Myalgia (2d - Fatal - **Results in Death**), Myocardial infarction (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **12088** | click or scan EU-EC-10009727312 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12089 | click or scan EU-EC-10009726819 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardioversion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**), Snoring (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12090 | click or scan EU-EC-10009726294 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (6d - Fatal - **Results in Death**, Other Medically Important Condition), Coma (6d - Fatal - **Results in Death**, Other Medically Important Condition), Death (6d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (6d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12091 | click or scan EU-EC-10009726045 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 12092 | click or scan EU-EC-10009726015 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12093 | click or scan EU-EC-10009725843 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Male | Meningoradiculitis (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12094 | click or scan EU-EC-10009725547 | | 2021-08-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12095 | click or scan EU-EC-10009725489 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Muscular weakness (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12096 | click or scan EU-EC-10009724964 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal distension (n/a - Recovering/Resolving - ), Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Choking (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mouth breathing (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Recovering/Resolving - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - ), Respiratory disorder (n/a - Recovering/Resolving - ), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12097 | click or scan EU-EC-10009724832 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12098 | click or scan EU-EC-10009724563 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - ), Coordination abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Encephalitis viral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Epilepsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Meningoencephalitis viral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12099 | click or scan EU-EC-10009724559 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Choking (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Reduced facial expression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination complication (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12100 | click or scan EU-EC-10009724411 | | 2021-08-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12101 | click or scan EU-EC-10009724099 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12102 | click or scan EU-EC-10009723880 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12103 | click or scan EU-EC-10009723876 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Plasmodium vivax infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12104 | click or scan EU-EC-10009723846 | | 2021-08-18 | Healthcare Professional | EEA | Not Specified | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Hypercholesterolaemia (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12105 | click or scan EU-EC-10009723812 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12106 | click or scan EU-EC-10009723644 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (68d - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic encephalopathy (68d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12107 | click or scan EU-EC-10009723405 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12108 | click or scan EU-EC-10009723324 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Autopsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epstein-Barr virus infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Histology (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12109 | click or scan EU-EC-10009723293 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic valve stenosis (7d - Fatal - **Results in Death**), Cardiac failure (7d - Fatal - **Results in Death**, Other Medically Important Condition), Emphysema (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12110 | click or scan EU-EC-10009723279 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12111 | click or scan EU-EC-10009723275 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12112 | click or scan EU-EC-10009723162 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 1 {DF} - Intramuscular]) |
| 12113 | click or scan EU-EC-10009723158 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [60d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12114 | click or scan EU-EC-10009723106 |  | 2021-08-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 12115 | click or scan EU-EC-10009722967 |  | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [71d - 1 {DF} - Intramuscular]) |
| 12116 | click or scan EU-EC-10009722280 |  | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12117 | click or scan EU-EC-10009721232 |  | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12118 | click or scan EU-EC-10009721192 |  | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (2d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (2d - Fatal - **Results in Death**), Panic attack (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12119 | click or scan EU-EC-10009721130 |  | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12120 | click or scan EU-EC-10009720952 |  | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12121 | click or scan EU-EC-10009720841 |  | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12122 | click or scan EU-EC-10009720583 |  | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12123 | click or scan EU-EC-10009720567 |  | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12124 | click or scan EU-EC-10009720256 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 12125 | click or scan EU-EC-10009720229 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12126 | click or scan EU-EC-10009720226 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Angioedema (1d - Recovered/Resolved - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Hypersensitivity (1d - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12127 | click or scan EU-EC-10009720165 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac output decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypophagia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12128 | click or scan EU-EC-10009719961 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12129 | click or scan EU-EC-10009719588 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Stupor (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12130 | click or scan EU-EC-10009719549 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12131 | click or scan EU-EC-10009719116 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12132 | click or scan EU-EC-10009718778 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a]) |
| 12133 | click or scan EU-EC-10009718757 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Systemic inflammatory response syndrome (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12134 | click or scan EU-EC-10009718563 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12135 | click or scan EU-EC-10009718186 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 12136 | click or scan EU-EC-10009718048 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Mental status changes (1d - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (1d - Unknown - Caused/Prolonged Hospitalisation), Surgery (12d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12137 | click or scan EU-EC-10009717833 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypopnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Osteomyelitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12138 | click or scan EU-EC-10009717788 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12139 | click or scan EU-EC-10009717656 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cholecystitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Liver disorder (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (0d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12140 | click or scan EU-EC-10009717647 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - Life Threatening), Hypertension (n/a - Fatal - **Results in Death**, Life Threatening), Maternal exposure during pregnancy (n/a - Unknown - Life Threatening), Nausea (n/a - Unknown - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12141 | click or scan EU-EC-10009717604 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Choking (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Speech disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12142 | click or scan EU-EC-10009717514 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Embolic stroke (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hospitalisation (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12143 | click or scan EU-EC-10009717480 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12144 | click or scan EU-EC-10009716959 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12145 | click or scan EU-EC-10009716898 | | 2021-08-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (2d - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**), Disseminated intravascular coagulation (2d - Fatal - **Results in Death**), Platelet count decreased (2d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Subcutaneous]) |
| 12146 | click or scan EU-EC-10009716897 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 12147 | click or scan EU-EC-10009716896 | | 2021-08-18 | Healthcare Professional | EEA | Not Specified | Not Specified | Death neonatal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transplacental]) |
| 12148 | click or scan EU-EC-10009716850 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12149 | click or scan EU-EC-10009716810 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12150 | click or scan EU-EC-10009716770 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12151 | click or scan EU-EC-10009716615 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12152 | click or scan EU-EC-10009716572 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12153 | click or scan EU-EC-10009716474 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12154 | click or scan EU-EC-10009716117 | | 2021-08-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Arthralgia (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Erythema (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Hiatus hernia (n/a - Unknown - ), Illness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Other Medically Important Condition), Vaccination complication (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12155 | click or scan EU-EC-10009716052 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12156 | click or scan EU-EC-10009715734 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12157 | click or scan EU-EC-10009715731 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Groin pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12158 | click or scan EU-EC-10009715631 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12159 | click or scan EU-EC-10009715619 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12160 | click or scan EU-EC-10009715618 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Illness (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12161 | click or scan EU-EC-10009715612 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12162 | click or scan EU-EC-10009715424 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Blood pressure increased (n/a - Unknown - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Ischaemia (n/a - Unknown - ), Lung disorder (n/a - Unknown - ), Renal disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12163 | click or scan EU-EC-10009715421 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12164 | click or scan EU-EC-10009715042 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12165 | click or scan EU-EC-10009714961 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (18d - Fatal - **Results in Death**), Nausea (18d - Fatal - **Results in Death**), Pyrexia (18d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 12166 | click or scan EU-EC-10009714430 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (10d - Fatal - **Results in Death**), Diarrhoea (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), Fatigue (10d - Fatal - **Results in Death**), Lung opacity (10d - Fatal - **Results in Death**), Nausea (10d - Fatal - **Results in Death**), Pain (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12167 | click or scan EU-EC-10009713051 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - ), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Joint stiffness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12168 | click or scan EU-EC-10009714260 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12169 | click or scan EU-EC-10009713988 | | 2021-08-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12170 | click or scan EU-EC-10009713543 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12171 | click or scan EU-EC-10009713161 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Acute hepatic failure (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neurological decompensation (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12172 | click or scan EU-EC-10009712759 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12173 | click or scan EU-EC-10009712593 | | 2021-08-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12174 | click or scan EU-EC-10009712240 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - ), Syncope (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12175 | click or scan EU-EC-10009712179 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - ), Arthralgia (n/a - Unknown - ), Delirium (n/a - Unknown - ), Ecchymosis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - Life Threatening), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Sputum retention (n/a - Unknown - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12176 | click or scan EU-EC-10009711938 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anal incontinence (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**), Pupillary reflex impaired (0d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| 12177 | click or scan EU-EC-10009711563 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Enterocolitis (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12178 | click or scan EU-EC-10009711303 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12179 | click or scan EU-EC-10009711211 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (10d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12180 | click or scan EU-EC-10009711180 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain death (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Motor dysfunction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ donor (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiration abnormal (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Snoring (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Trismus (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12181 | click or scan EU-EC-10009711172 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Intestinal obstruction (64d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urinary tract infection (64d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Vomiting (64d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12182 | click or scan EU-EC-10009711114 |  | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12183 | click or scan EU-EC-10009710765 |  | 2021-08-17 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Azotaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperlactacidaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Personality change (n/a - Recovered/Resolved - ), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12184 | click or scan EU-EC-10009710599 |  | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12185 | click or scan EU-EC-10009710584 |  | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |
| 12186 | click or scan EU-EC-10009710578 |  | 2021-08-17 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 12187 | click or scan EU-EC-10009709960 |  | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12188 | click or scan EU-EC-10009709697 |  | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12189 | click or scan EU-EC-10009709663 |  | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12190 | click or scan EU-EC-10009709233 |  | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Haemoptysis (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 12191 | click or scan EU-EC-10009709175 |  | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12192 | click or scan EU-EC-10009709021 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cold sweat (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12193 | click or scan EU-EC-10009708594 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dysphonia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hiccups (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 12194 | click or scan EU-EC-10009708478 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vaccination site swelling (n/a - Recovered/Resolved - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12195 | click or scan EU-EC-10009708429 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinusitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12196 | click or scan EU-EC-10009708304 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12197 | click or scan EU-EC-10009708249 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 12198 | click or scan EU-EC-10009708204 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 12199 | click or scan EU-EC-10009708168 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12200 | click or scan EU-EC-10009707799 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Language disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12201 | click or scan EU-EC-10009707796 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 12202 | click or scan EU-EC-10009707795 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 12203 | click or scan EU-EC-10009707794 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12204 | click or scan EU-EC-10009707783 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lactic acidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash (n/a - Fatal - **Results in Death**), Rash erythematous (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rheumatoid arthritis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12205 | click or scan EU-EC-10009707772 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin lesion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12206 | click or scan EU-EC-10009707675 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12207 | click or scan EU-EC-10009707610 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12208 | click or scan EU-EC-10009706809 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12209 | click or scan EU-EC-10009706690 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Vaccination site pain (2d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12210 | click or scan EU-EC-10009706618 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Unevaluable event (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12211 | click or scan EU-EC-10009706617 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12212 | click or scan EU-EC-10009706584 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12213 | click or scan EU-EC-10009706576 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12214 | click or scan EU-EC-10009706466 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12215 | click or scan EU-EC-10009706464 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12216 | click or scan EU-EC-10009706413 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12217 | click or scan EU-EC-10009706412 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Hypersensitivity (4d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12218 | click or scan EU-EC-10009706383 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12219 | click or scan EU-EC-10009706376 | | 2021-08-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12220 | click or scan EU-EC-10009706370 | | 2021-08-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12221 | click or scan EU-EC-10009706325 |  | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12222 | click or scan EU-EC-10009706323 |  | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12223 | click or scan EU-EC-10009706142 |  | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12224 | click or scan EU-EC-10009705979 |  | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12225 | click or scan EU-EC-10009705694 |  | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12226 | click or scan EU-EC-10009705642 |  | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12227 | click or scan EU-EC-10009705615 |  | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Gastrointestinal haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12228 | click or scan EU-EC-10009705614 |  | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Recovered/Resolved - ), Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (2d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1min - 1 {DF} - Intramuscular]) |
| 12229 | click or scan EU-EC-10009705479 |  | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12230 | click or scan EU-EC-10009705180 |  | 2021-08-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12231 | click or scan EU-EC-10009705161 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aggression (n/a - Unknown - ), Cellulitis (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12232 | click or scan EU-EC-10009705144 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12233 | click or scan EU-EC-10009705093 | | 2021-08-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12234 | click or scan EU-EC-10009704447 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12235 | click or scan EU-EC-10009704289 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arterial thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Carotid artery thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular insufficiency (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gastrointestinal sounds abnormal (n/a - Unknown - ), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - ), Platelet disorder (n/a - Unknown - Other Medically Important Condition), Pupil fixed (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupillary reflex impaired (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12236 | click or scan EU-EC-10009703982 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12237 | click or scan EU-EC-10009703789 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (26d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12238 | click or scan EU-EC-10009703522 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung consolidation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia pneumococcal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12239 | click or scan EU-EC-10009702873 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12240 | click or scan EU-EC-10009702750 | | 2021-08-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12241 | click or scan EU-EC-10009702686 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Apnoea (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12242 | click or scan EU-EC-10009702648 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (0d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 12243 | click or scan EU-EC-10009702054 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12244 | click or scan EU-EC-10009701686 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (106d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain neoplasm (87d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (87d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12245 | click or scan EU-EC-10009701467 | | 2021-08-16 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12246 | click or scan EU-EC-10009701420 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12247 | click or scan EU-EC-10009701419 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic encephalopathy (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12248 | click or scan EU-EC-10009701348 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Diabetes mellitus inadequate control (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12249 | click or scan EU-EC-10009701335 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12250 | click or scan EU-EC-10009701033 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vascular dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12251 | click or scan EU-EC-10009700803 | | 2021-08-16 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haematoma (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chills (n/a - Recovering/Resolving - ), Haematoma (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Pain (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12252 | click or scan EU-EC-10009700049 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12253 | click or scan EU-EC-10009699810 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Recovered/Resolved - ), Dyspnoea (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12254 | click or scan EU-EC-10009699772 | | 2021-08-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Lung neoplasm malignant (n/a - Fatal - **Results in Death**), Neoplasm progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12255 | click or scan EU-EC-10009699437 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Ascites (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**), Pharyngeal oedema (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12256 | click or scan EU-EC-10009699296 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12257 | click or scan EU-EC-10009699123 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12258 | click or scan EU-EC-10009698859 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12259 | click or scan EU-EC-10009698838 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12260 | click or scan EU-EC-10009698717 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12261 | click or scan EU-EC-10009698712 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrooesophageal reflux disease (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12262 | click or scan EU-EC-10009698667 | | 2021-08-16 | Healthcare Professional | EEA | Not Specified | Female | Anuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 12263 | click or scan EU-EC-10009698587 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12264 | click or scan EU-EC-10009698586 | | 2021-08-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [1d - 1 {DF} - n/a]) |
| 12265 | click or scan EU-EC-10009698580 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12266 | click or scan EU-EC-10009698536 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12267 | click or scan EU-EC-10009698526 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [29d - 1 {DF} - Intramuscular]) |
| 12268 | click or scan EU-EC-10009698495 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12269 | click or scan EU-EC-10009698394 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12270 | click or scan EU-EC-10009698369 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12271 | click or scan EU-EC-10009698208 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12272 | click or scan EU-EC-10009697793 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Urinary tract infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12273 | click or scan EU-EC-10009697787 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12274 | click or scan EU-EC-10009697770 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12275 | click or scan EU-EC-10009697727 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12276 | click or scan EU-EC-10009697714 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12277 | click or scan EU-EC-10009697649 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic reaction (6h - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12278 | click or scan EU-EC-10009697326 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12279 | click or scan EU-EC-10009696643 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12280 | click or scan EU-EC-10009696627 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac hypertrophy (n/a - Fatal - **Results in Death**, Life Threatening), Cardiomegaly (n/a - Fatal - **Results in Death**, Life Threatening), Cholelithiasis (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Obesity (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening), Renal cyst (n/a - Fatal - **Results in Death**, Life Threatening), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) DISPERSION FOR INJECTION [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| 12281 | click or scan EU-EC-10009696571 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fluid retention (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12282 | click or scan EU-EC-10009696550 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12283 | click or scan EU-EC-10009696407 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12284 | click or scan EU-EC-10009696068 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12285 | click or scan EU-EC-10009695609 | | 2021-08-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Bladder disorder (n/a - Unknown - ), Cough (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Prostatic disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12286 | click or scan EU-EC-10009695559 |  | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypoglycaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Presyncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12287 | click or scan EU-EC-10009695547 |  | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Multiple system atrophy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12288 | click or scan EU-EC-10009695498 |  | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12289 | click or scan EU-EC-10009695446 |  | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12290 | click or scan EU-EC-10009695365 |  | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (5d - Unknown - Life Threatening), Chills (5d - Unknown - Life Threatening), Death (5d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (5d - Unknown - Life Threatening), Pain (5d - Unknown - Life Threatening), Pyrexia (5d - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12291 | click or scan EU-EC-10009694713 |  | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12292 | click or scan EU-EC-10009694525 |  | 2021-08-16 | Healthcare Professional | Non EEA | Not Specified | Female | Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12293 | click or scan EU-EC-10009694063 |  | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12294 | click or scan EU-EC-10009694045 |  | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12295 | click or scan EU-EC-10009693673 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Areflexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Blood sodium decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Constipation (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hilar lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Retroperitoneal lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sensory loss (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Splenomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12296 | click or scan EU-EC-10009693665 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Inappropriate schedule of product administration (n/a - Unknown - ), Small for dates baby (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 12297 | click or scan EU-EC-10009693146 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 12298 | click or scan EU-EC-10009693143 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Insomnia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12299 | click or scan EU-EC-10009693111 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12300** | click or scan EU-EC-10009693099 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle twitching (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle twitching (n/a - Unknown - ), Off label use (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Skull fracture (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Traumatic haemorrhage (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12301** | click or scan EU-EC-10009693090 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12302** | click or scan EU-EC-10009693062 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12303** | click or scan EU-EC-10009693053 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Hallucination (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12304** | click or scan EU-EC-10009692178 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12305** | click or scan EU-EC-10009692176 | | 2021-08-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Anosmia (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Subdural haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12306** | click or scan EU-EC-10009691764 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12307** | click or scan EU-EC-10009691740 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12308** | click or scan EU-EC-10009691594 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12309** | click or scan EU-EC-10009691550 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12310** | click or scan EU-EC-10009691510 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Pain (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12311** | click or scan EU-EC-10009691327 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12312** | click or scan EU-EC-10009691140 | | 2021-08-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (9d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Coagulopathy (9d - Fatal - **Results in Death**, Other Medically Important Condition), Epistaxis (n/a - Unknown - ), Haematoma (n/a - Unknown - Other Medically Important Condition), Haemorrhage (n/a - Unknown - ), Headache (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Paraparesis (n/a - Unknown - Other Medically Important Condition), Puncture site haemorrhage (n/a - Unknown - Other Medically Important Condition), Pupils unequal (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Quadriplegia (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **12313** | click or scan EU-EC-10009691104 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **12314** | click or scan EU-EC-10009690812 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **12315** | click or scan EU-EC-10009690789 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **12316** | click or scan EU-EC-10009688843 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abnormal loss of weight (n/a - Not Recovered/Not Resolved - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Chromaturia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Epstein-Barr virus infection (n/a - Not Recovered/Not Resolved - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**), Haemophagocytic lymphohistiocytosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Insomnia (n/a - Not Recovered/Not Resolved - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**), Rheumatoid arthritis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12317** | click or scan EU-EC-10009688842 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Ventricular hypertrophy (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12318 | click or scan EU-EC-10009688835 | | 2021-08-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Anisocytosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), End stage renal disease (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell elliptocytes present (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell morphology abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell target cells present (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Rouleaux formation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12319 | click or scan EU-EC-10009688826 | | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac valve disease (n/a - Not Recovered/Not Resolved - **Results in Death**), Encephalitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12320 | click or scan EU-EC-10009688660 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (7d - Not Recovered/Not Resolved - **Results in Death**), Diarrhoea (1wk - Not Recovered/Not Resolved - **Results in Death**), Pain in extremity (1wk - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (7d - Fatal - **Results in Death**), Renal infarct (n/a - Not Recovered/Not Resolved - **Results in Death**), Splenic infarction (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]) |
| 12321 | click or scan EU-EC-10009688656 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**), Cerebrovascular accident (8d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12322 | click or scan EU-EC-10009688350 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myeloid leukaemia (69d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 12323 | click or scan EU-EC-10009688336 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemophagocytic lymphohistiocytosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemophagocytic lymphohistiocytosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 12324 | click or scan EU-EC-10009688325 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Unknown - **Results in Death**), Cardiac arrest (n/a - Unknown - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**), Coronary artery thrombosis (3d - Fatal - **Results in Death**), Ischaemia (n/a - Unknown - **Results in Death**), Rectal haemorrhage (n/a - Unknown - **Results in Death**), Shock (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**), Thrombosis mesenteric vessel (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12325 | click or scan EU-EC-10009688163 | | 2021-08-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (31d - Not Recovered/Not Resolved - **Results in Death**), Death (2527d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 12326 | click or scan EU-EC-10009687983 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12327 | click or scan EU-EC-10009687484 |  | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (2d - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (2d - Recovered/Resolved - ), Diarrhoea (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Pain in extremity (2d - Recovered/Resolved - ), Vomiting (2d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 12328 | click or scan EU-EC-10009687338 |  | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atelectasis (1d - Fatal - **Results in Death**), Cardiomegaly (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Lung opacity (1d - Fatal - **Results in Death**), Oedema (1d - Fatal - **Results in Death**), Pleural effusion (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12329 | click or scan EU-EC-10009687321 |  | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12330 | click or scan EU-EC-10009687315 |  | 2021-08-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain lower (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Back pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Febrile neutropenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Illness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Non-Hodgkin's lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12331 | click or scan EU-EC-10009687310 |  | 2021-08-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Axillary pain (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Bladder hypertrophy (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Herpes zoster (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Injection site mass (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Lymphadenectomy (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Mental status changes (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Oedema (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Pulmonary artery dilatation (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary hypertension (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary mass (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Retroperitoneal lymphadenopathy (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Splenic lesion (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Tenderness (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Urinary tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12332 | click or scan EU-EC-10009687268 |  | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 12333 | click or scan EU-EC-10009687149 |  | 2021-08-14 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12334 | click or scan EU-EC-10009686455 |  | 2021-08-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12335 | click or scan EU-EC-10009685820 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12336 | click or scan EU-EC-10009685419 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 12337 | click or scan EU-EC-10009685165 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sputum increased (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12338 | click or scan EU-EC-10009684820 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12339 | click or scan EU-EC-10009684641 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Drug reaction with eosinophilia and systemic symptoms (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12340 | click or scan EU-EC-10009684628 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12341 | click or scan EU-EC-10009684578 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Taste disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12342 | click or scan EU-EC-10009684012 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paresis (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12343 | click or scan EU-EC-10009683705 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12344 | click or scan EU-EC-10009683184 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12345 | click or scan EU-EC-10009682146 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiomegaly (n/a - Fatal - **Results in Death**), Congestive hepatopathy (n/a - Fatal - **Results in Death**), Kidney congestion (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12346 | click or scan EU-EC-10009682135 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12347 | click or scan EU-EC-10009682081 | | 2021-08-13 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 12348 | click or scan EU-EC-10009682062 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (24h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 12349 | click or scan EU-EC-10009681986 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12350 | click or scan EU-EC-10009681956 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12351 | click or scan EU-EC-10009681890 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12352 | click or scan EU-EC-10009681701 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Pancreatitis acute (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12353 | click or scan EU-EC-10009681611 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Congestive cardiomyopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12354 | click or scan EU-EC-10009681609 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Emphysema (n/a - Fatal - **Results in Death**), Pulmonary fibrosis (n/a - Fatal - **Results in Death**), Pulmonary hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12355 | click or scan EU-EC-10009681021 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arterial thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular]) |
| 12356 | click or scan EU-EC-10009680970 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Aortic rupture (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12357 | click or scan EU-EC-10009680877 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 12358 | click or scan EU-EC-10009680855 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Seizure (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12359 | click or scan EU-EC-10009680850 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Neurodegenerative disorder (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Swelling (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12360 | click or scan EU-EC-10009680506 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (0d - Fatal - **Results in Death**), Circulatory collapse (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12361 | click or scan EU-EC-10009680330 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12362 | click or scan EU-EC-10009679774 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12363 | click or scan EU-EC-10009679665 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12364 | click or scan EU-EC-10009679578 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12365 | click or scan EU-EC-10009679572 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12366 | click or scan EU-EC-10009679255 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Unevaluable event (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 12367 | click or scan EU-EC-10009679194 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Neuralgic amyotrophy (n/a - Fatal - **Results in Death**, Disabling), Paralysis (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12368 | click or scan EU-EC-10009679174 | | 2021-08-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12369 | click or scan EU-EC-10009679000 | | 2021-08-13 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12370 | click or scan EU-EC-10009678974 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12371 | click or scan EU-EC-10009678913 | | 2021-08-13 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12372 | click or scan EU-EC-10009678898 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Unevaluable event (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12373 | click or scan EU-EC-10009678740 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12374 | click or scan EU-EC-10009678492 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12375 | click or scan EU-EC-10009678473 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 12376 | click or scan EU-EC-10009678396 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12377 | click or scan EU-EC-10009678390 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cellulitis (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12378 | click or scan EU-EC-10009678215 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12379 | click or scan EU-EC-10009678136 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12380 | click or scan EU-EC-10009677966 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (2d - Fatal - **Results in Death**), Back pain (2d - Fatal - **Results in Death**), Cardiovascular disorder (2d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diplegia (1d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Monoplegia (1d - Fatal - **Results in Death**), Renal failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12381 | click or scan EU-EC-10009677767 | | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (39990min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchospasm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sneezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Taste disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12382 | click or scan EU-EC-10009677762 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12383 | click or scan EU-EC-10009677441 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12384 | click or scan EU-EC-10009677360 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Leukoencephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12385 | click or scan EU-EC-10009677335 |  | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Blood fibrinogen increased (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**), Retrograde amnesia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Snoring (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12386 | click or scan EU-EC-10009677105 |  | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [5s - 1 {DF} - Intramuscular]) |
| 12387 | click or scan EU-EC-10009676982 |  | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Death (2d - Fatal - **Results in Death**), Nervous system disorder (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12388 | click or scan EU-EC-10009676937 |  | 2021-08-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Blindness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Delusion (n/a - Not Recovered/Not Resolved - ), Dysphagia (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscle spasms (1wk - Recovered/Resolved - Caused/Prolonged Hospitalisation), Panic attack (n/a - Not Recovered/Not Resolved - ), Status epilepticus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12389 | click or scan EU-EC-10009676897 |  | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Facial asymmetry (n/a - Unknown - ), Facial spasm (n/a - Unknown - ), Hypotension (1d - Recovered/Resolved - ), Somnolence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12390 | click or scan EU-EC-10009676863 |  | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | Carditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12391 | click or scan EU-EC-10009676535 |  | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (3d - Unknown - ), Pyrexia (3d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12392 | click or scan EU-EC-10009676509 |  | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Thrombotic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12393 | click or scan EU-EC-10009676501 |  | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Oesophageal carcinoma (n/a - Unknown - Other Medically Important Condition), Paralysis (n/a - Unknown - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12394 | click or scan EU-EC-10009676372 |  | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Nervous system disorder (1d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12395 | click or scan EU-EC-10009676127 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Malaise (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12396 | click or scan EU-EC-10009676112 | | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Headache (9d - Fatal - **Results in Death**), Subarachnoid haemorrhage (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12397 | click or scan EU-EC-10009676103 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Septic shock (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12398 | click or scan EU-EC-10009676017 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oral fungal infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory moniliasis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superinfection bacterial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12399 | click or scan EU-EC-10009676014 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Pulmonary pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12400 | click or scan EU-EC-10009675605 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Fall (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12401 | click or scan EU-EC-10009675595 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12402 | click or scan EU-EC-10009675474 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12403** | click or scan EU-EC-10009675468 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cerebral haematoma (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Fatal - **Results in Death**), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Renal infarct (n/a - Fatal - **Results in Death**), Renal vein thrombosis (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Splenic infarction (n/a - Fatal - **Results in Death**), Splenic vein thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Venous occlusion (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12404** | click or scan EU-EC-10009675319 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chills (17d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (17d - Fatal - **Results in Death**), Headache (17d - Fatal - **Results in Death**), Malaise (17d - Fatal - **Results in Death**), Myalgia (17d - Fatal - **Results in Death**), Nausea (17d - Fatal - **Results in Death**), Pyrexia (17d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12405** | click or scan EU-EC-10009674824 | | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Leukaemia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12406** | click or scan EU-EC-10009674822 | | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Nipple pain (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12407** | click or scan EU-EC-10009674751 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Brain death (2wk - Fatal - **Results in Death**), Cerebral venous thrombosis (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - ), Vision blurred (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **12408** | click or scan EU-EC-10009674295 | | 2021-08-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (79d - Fatal - **Results in Death**), Loss of consciousness (79d - Fatal - **Results in Death**), Peripheral swelling (79d - Fatal - **Results in Death**), Pyrexia (79d - Fatal - **Results in Death**), Tremor (79d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **12409** | click or scan EU-EC-10009674256 | | 2021-08-13 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12410** | click or scan EU-EC-10009673553 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12411** | click or scan EU-EC-10009673385 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure acute (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (0d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12412 | click or scan EU-EC-10009673133 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 100ug - Intramuscular]) |
| 12413 | click or scan EU-EC-10009672980 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (2h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 100ug - Intramuscular - More in ICSR]) |
| 12414 | click or scan EU-EC-10009672260 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12415 | click or scan EU-EC-10009672256 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (2d - Fatal - **Results in Death**), Fatigue (2d - Fatal - **Results in Death**), Pain (2d - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12416 | click or scan EU-EC-10009672254 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12417 | click or scan EU-EC-10009672229 | | 2021-08-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12418 | click or scan EU-EC-10009671307 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12419 | click or scan EU-EC-10009671154 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [SUMATRIPTAN] (S - Migraine - Unknown - [n/a - 100mg - Oral]) |
| 12420 | click or scan EU-EC-10009670757 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (2d - Fatal - **Results in Death**), Embolic stroke (2d - Fatal - **Results in Death**), Embolism venous (2d - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Unknown - **Results in Death**), Pulmonary embolism (2d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12421 | click or scan EU-EC-10009670682 | | 2021-08-12 | Non Healthcare Professional | EEA | Not Specified | Male | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12422 | click or scan EU-EC-10009670579 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atypical pneumonia (n/a - Unknown - Other Medically Important Condition), Blood pressure increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Dehydration (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Unknown - ), Lung infiltration (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12423 | click or scan EU-EC-10009670445 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]), FILGRASTIM [FILGRASTIM] (S - Haematopoietic stem cell mobilisation - Not applicable - [4d - 600ug - Unknown]) |
| 12424 | click or scan EU-EC-10009670051 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [29d - 1{DF} - Intramuscular - More in ICSR]) |
| 12425 | click or scan EU-EC-10009670009 | | 2021-08-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12426 | click or scan EU-EC-10009669573 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bacterial sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12427 | click or scan EU-EC-10009668410 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [43d - 2{DF} - Intramuscular]) |
| 12428 | click or scan EU-EC-10009668394 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12429 | click or scan EU-EC-10009668300 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Systemic lupus erythematosus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - 2{DF} - Intramuscular]) |
| 12430 | click or scan EU-EC-10009668223 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 12431 | click or scan EU-EC-10009668005 | | 2021-08-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12432 | click or scan EU-EC-10009667788 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12433** | click or scan EU-EC-10009666774 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bacterial sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Hypotension (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Procalcitonin increased (n/a - Unknown - ), Pulmonary sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Respiratory acidosis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12434** | click or scan EU-EC-10009666762 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12435** | click or scan EU-EC-10009666762 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12436** | click or scan EU-EC-10009666744 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12437** | click or scan EU-EC-10009666738 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Agitation (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12438** | click or scan EU-EC-10009666290 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12439** | click or scan EU-EC-10009666271 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12440** | click or scan EU-EC-10009666267 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vision blurred (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12441 | click or scan EU-EC-10009666164 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Blister (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Skin weeping (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 12442 | click or scan EU-EC-10009665794 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Oesophageal varices haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12443 | click or scan EU-EC-10009665764 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Concomitant disease progression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12444 | click or scan EU-EC-10009665394 | | 2021-08-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12445 | click or scan EU-EC-10009665383 | | 2021-08-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12446 | click or scan EU-EC-10009665359 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12447 | click or scan EU-EC-10009665127 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - ), Muscular weakness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12448 | click or scan EU-EC-10009665043 | | 2021-08-12 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12449 | click or scan EU-EC-10009665011 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Influenza like illness (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12450 | click or scan EU-EC-10009664894 | | 2021-08-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12451 | click or scan EU-EC-10009664893 | | 2021-08-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12452 | click or scan EU-EC-10009664710 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12453 | click or scan EU-EC-10009664549 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Fibrin D dimer increased (1d - Fatal - **Results in Death**), Leukocytosis (1d - Fatal - **Results in Death**), Neutrophilia (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**), Urinary tract infection (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12454 | click or scan EU-EC-10009664203 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12455 | click or scan EU-EC-10009664188 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12456 | click or scan EU-EC-10009664107 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Monoparesis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Photophobia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Testicular pain (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12457 | click or scan EU-EC-10009663719 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12458 | click or scan EU-EC-10009663700 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Injection site haematoma (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12459 | click or scan EU-EC-10009663278 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Acute abdomen (4d - Fatal - **Results in Death**), Acute myocardial infarction (4d - Fatal - **Results in Death**), Cerebral infarction (4d - Fatal - **Results in Death**), Intestinal ischaemia (4d - Fatal - **Results in Death**), Mesenteric artery stent insertion (4d - Fatal - **Results in Death**), Pupils unequal (4d - Fatal - **Results in Death**), Renal infarct (4d - Fatal - **Results in Death**), Shock (4d - Fatal - **Results in Death**), Splenic infarction (4d - Fatal - **Results in Death**), Thrombectomy (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12460 | click or scan EU-EC-10009663046 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12461 | click or scan EU-EC-10009663036 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12462 | click or scan EU-EC-10009663033 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12463 | click or scan EU-EC-10009663027 |  | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12464 | click or scan EU-EC-10009662582 |  | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12465 | click or scan EU-EC-10009662571 |  | 2021-08-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12466 | click or scan EU-EC-10009662567 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12467 | click or scan EU-EC-10009662563 |  | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12468 | click or scan EU-EC-10009662562 |  | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased activity (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12469 | click or scan EU-EC-10009662557 |  | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Brain injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Lung consolidation (n/a - Unknown - Other Medically Important Condition), Post cardiac arrest syndrome (n/a - Fatal - **Results in Death**), Rib fracture (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12470** | click or scan EU-EC-10009662550 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12471** | click or scan EU-EC-10009662548 |  | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12472** | click or scan EU-EC-10009662536 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12473** | click or scan EU-EC-10009662319 |  | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Injection site discomfort (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12474** | click or scan EU-EC-10009661935 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12475** | click or scan EU-EC-10009661627 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12476** | click or scan EU-EC-10009661626 |  | 2021-08-12 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Coagulopathy (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12477** | click or scan EU-EC-10009661612 |  | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12478** | click or scan EU-EC-10009661601 |  | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12479** | click or scan EU-EC-10009661466 |  | 2021-08-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coagulopathy (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Night sweats (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Red blood cell count increased (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12480** | click or scan EU-EC-10009661072 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Ascites (54d - Fatal - **Results in Death**), Metastases to liver (54d - Fatal - **Results in Death**), Metastases to lung (54d - Fatal - **Results in Death**), Metastases to lymph nodes (54d - Fatal - **Results in Death**), Metastases to the mediastinum (54d - Fatal - **Results in Death**), Pancreatic carcinoma (54d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| **12481** | click or scan EU-EC-10009660858 | | 2021-08-12 | Healthcare Professional | EEA | More than 85 Years | Female | Unresponsive to stimuli (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **12482** | click or scan EU-EC-10009660857 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haematoma (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **12483** | click or scan EU-EC-10009660838 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **12484** | click or scan EU-EC-10009660814 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Back pain (0d - Fatal - **Results in Death**), Hyperthermia (0d - Fatal - **Results in Death**), Pain in extremity (0d - Fatal - **Results in Death**), Terminal state (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **12485** | click or scan EU-EC-10009659137 | | 2021-08-11 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **12486** | click or scan EU-EC-10009659037 | | 2021-08-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **12487** | click or scan EU-EC-10009658476 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Male | Bradykinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cognitive disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **12488** | click or scan EU-EC-10009657404 | | 2021-08-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (5d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ), Malaise (5d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (8d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (5d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12489** | click or scan EU-EC-10009657250 | | 2021-08-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhagic transformation stroke (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Other Medically Important Condition), Intracranial pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **12490** | click or scan EU-EC-10009657248 | | 2021-08-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **12491** | click or scan EU-EC-10009657239 | | 2021-08-11 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **12492** | click or scan EU-EC-10009656345 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Disseminated intravascular coagulation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Transient ischaemic attack - Drug withdrawn - [n/a - 1{DF} - Oral]) |
| **12493** | click or scan EU-EC-10009656316 | | 2021-08-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Hepatic vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Parenteral]) |
| **12494** | click or scan EU-EC-10009656310 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intradermal]) |
| **12495** | click or scan EU-EC-10009656281 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **12496** | click or scan EU-EC-10009655989 | | 2021-08-11 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **12497** | click or scan EU-EC-10009655977 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12498 | click or scan EU-EC-10009655950 | | 2021-08-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12499 | click or scan EU-EC-10009655809 | | 2021-08-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Anxiety (n/a - Unknown - ), Behaviour disorder (n/a - Unknown - ), Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depression (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Mood altered (n/a - Unknown - ), Oral mucosal blistering (n/a - Unknown - ), Suicidal ideation (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12500 | click or scan EU-EC-10009655688 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Activated partial thromboplastin time prolonged (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Activated partial thromboplastin time shortened (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Brain herniation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), C-reactive protein increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral mass effect (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Epilepsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Facial paresis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haptoglobin increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Nervous system disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Oliguria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12501 | click or scan EU-EC-10009655684 | | 2021-08-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 12502 | click or scan EU-EC-10009655596 | | 2021-08-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea exertional (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12503 | click or scan EU-EC-10009654648 | | 2021-08-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12504 | click or scan EU-EC-10009654208 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oral fungal infection (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12505 | click or scan EU-EC-10009654193 | | 2021-08-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (41d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12506 | click or scan EU-EC-10009653722 | | 2021-08-11 | Healthcare Professional | EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12507 | click or scan EU-EC-10009652203 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12508 | click or scan EU-EC-10009651639 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiorenal syndrome (2wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12509 | click or scan EU-EC-10009651580 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [2s - 1 {DF} - Intramuscular - More in ICSR]) |
| 12510 | click or scan EU-EC-10009651117 | | 2021-08-11 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 12511 | click or scan EU-EC-10009650892 | | 2021-08-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Cerebral artery thrombosis (2d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Thrombocytopenia (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12512 | click or scan EU-EC-10009647587 | | 2021-08-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Bacterial infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood loss anaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12513 | click or scan EU-EC-10009646900 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (0d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12514 | click or scan EU-EC-10009646888 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Female | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12515 | click or scan EU-EC-10009645689 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular insufficiency (n/a - Unknown - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flank pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 12516 | click or scan EU-EC-10009644745 | | 2021-08-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12517 | click or scan EU-EC-10009644316 | | 2021-08-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12518 | click or scan EU-EC-10009644245 | | 2021-08-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12519 | click or scan EU-EC-10009644025 | | 2021-08-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12520 | click or scan EU-EC-10009643547 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Gastrointestinal haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12521 | click or scan EU-EC-10009643475 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [VALACICLOVIR] (S - COVID-19 immunisation - Not applicable - [4d - 1 {DF} - Oral]) |
| 12522 | click or scan EU-EC-10009643474 | | 2021-08-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Parenteral]) |
| 12523 | click or scan EU-EC-10009643472 | | 2021-08-10 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 12524 | click or scan EU-EC-10009643379 | | 2021-08-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12525 | click or scan EU-EC-10009643370 | | 2021-08-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12526 | click or scan EU-EC-10009643334 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Prophylaxis - n/a - [1d - .5mL - n/a]), [NEFOPAM, NEFOPAM HYDROCHLORIDE] (S - Abdominal pain - n/a - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (S - Abdominal pain - n/a - [n/a - n/a - n/a]) |
| 12527 | click or scan EU-EC-10009643325 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12528 | click or scan EU-EC-10009643323 | | 2021-08-10 | Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12529 | click or scan EU-EC-10009643321 | | 2021-08-10 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), General physical health deterioration (1wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 12530 | click or scan EU-EC-10009643002 | | 2021-08-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Colitis ischaemic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12531 | click or scan EU-EC-10009641563 | | 2021-08-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12532 | click or scan EU-EC-10009641462 | | 2021-08-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12533 | click or scan EU-EC-10009641141 | | 2021-08-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac myxoma (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12534 | click or scan EU-EC-10009640921 | | 2021-08-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 12535 | click or scan EU-EC-10009640462 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 12536 | click or scan EU-EC-10009639852 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), PANITUMUMAB [PANITUMUMAB] (S - Colon cancer metastatic - Drug withdrawn - [n/a - n/a - Unknown]) |
| 12537 | click or scan EU-EC-10009639468 | | 2021-08-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12538 | click or scan EU-EC-10009638137 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 12539 | click or scan EU-EC-10009637709 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| 12540 | click or scan EU-EC-10009637503 | | 2021-08-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hyperventilation (n/a - Unknown - ), Productive cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**), Restlessness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 12541 | click or scan EU-EC-10009634860 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12542 | click or scan EU-EC-10009634842 | | 2021-08-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (30d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (30d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12543 | click or scan EU-EC-10009634699 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Anti-platelet antibody (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Portosplenomesenteric venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12544 | click or scan EU-EC-10009634544 | | 2021-08-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Choking sensation (n/a - Fatal - **Results in Death**), Fatigue (n/a - Recovered/Resolved - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12545 | click or scan EU-EC-10009633787 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12546 | click or scan EU-EC-10009633474 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12547 | click or scan EU-EC-10009633375 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12548 | click or scan EU-EC-10009633257 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Mucormycosis (n/a - Not Recovered/Not Resolved - ), Septic shock (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12549 | click or scan EU-EC-10009633054 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12550 | click or scan EU-EC-10009632905 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12551 | click or scan EU-EC-10009632237 | | 2021-08-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12552 | click or scan EU-EC-10009631839 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12553 | click or scan EU-EC-10009631835 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 12554 | click or scan EU-EC-10009631756 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12555 | click or scan EU-EC-10009631722 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [29d - 2{DF} - Intramuscular]) |
| 12556 | click or scan EU-EC-10009631670 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 12557 | click or scan EU-EC-10009631637 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [24d - 2{DF} - Intramuscular]) |
| 12558 | click or scan EU-EC-10009631635 | | 2021-08-09 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| 12559 | click or scan EU-EC-10009631573 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Delirium tremens (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12560 | click or scan EU-EC-10009631545 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Adrenal mass (0d - Fatal - **Results in Death**), Aortic arteriosclerosis (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Cardiac ventricular thrombosis (0d - Fatal - **Results in Death**), Diarrhoea (0d - Fatal - **Results in Death**), Gastrointestinal haemorrhage (0d - Fatal - **Results in Death**), Hepatic mass (0d - Fatal - **Results in Death**), Hepatomegaly (0d - Fatal - **Results in Death**), Hypotension (0d - Fatal - **Results in Death**), Pulmonary artery thrombosis (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Renal vascular thrombosis (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12561 | click or scan EU-EC-10009631542 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12562 | click or scan EU-EC-10009631388 | | 2021-08-09 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12563 | click or scan EU-EC-10009631288 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12564 | click or scan EU-EC-10009631283 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12565 | click or scan EU-EC-10009631261 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12566 | click or scan EU-EC-10009631239 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12567 | click or scan EU-EC-10009631214 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12568 | click or scan EU-EC-10009630725 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vaccination site haematoma (n/a - Unknown - ) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12569 | click or scan EU-EC-10009630462 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Female | Anaemia (83d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling hot (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ), Thrombocytopenia (83d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site haematoma (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaginal haemorrhage (2d - Recovered/Resolved - ), White blood cell disorder (83d - Unknown - ) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12570 | click or scan EU-EC-10009629835 | | 2021-08-09 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12571 | click or scan EU-EC-10009629814 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure increased (n/a - Unknown - ), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12572 | click or scan EU-EC-10009629812 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12573 | click or scan EU-EC-10009629794 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Other Medically Important Condition), Hypopnoea (n/a - Unknown - Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12574 | click or scan EU-EC-10009629648 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Rash (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12575 | click or scan EU-EC-10009629615 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12576 | click or scan EU-EC-10009629614 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12577 | click or scan EU-EC-10009629613 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12578 | click or scan EU-EC-10009629605 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12579 | click or scan EU-EC-10009629601 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12580 | click or scan EU-EC-10009629496 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Influenza like illness (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12581 | click or scan EU-EC-10009629477 | | 2021-08-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12582 | click or scan EU-EC-10009629337 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12583 | click or scan EU-EC-10009629330 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12584 | click or scan EU-EC-10009629264 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12585 | click or scan EU-EC-10009629152 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12586 | click or scan EU-EC-10009629065 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12587 | click or scan EU-EC-10009628763 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic cerebral infarction (53d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12588 | click or scan EU-EC-10009628324 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12589 | click or scan EU-EC-10009628279 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Injection site haematoma (n/a - Fatal - **Results in Death**), Injection site inflammation (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Injection site warmth (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12590 | click or scan EU-EC-10009628196 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12591 | click or scan EU-EC-10009627995 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12592 | click or scan EU-EC-10009627644 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12593 | click or scan EU-EC-10009627631 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypokalaemia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12594 | click or scan EU-EC-10009627611 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure immeasurable (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (n/a - Fatal - **Results in Death**), Moaning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12595 | click or scan EU-EC-10009627594 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12596 | click or scan EU-EC-10009626736 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12597 | click or scan EU-EC-10009626714 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Blood albumin decreased (n/a - Fatal - **Results in Death**), Capillary leak syndrome (n/a - Fatal - **Results in Death**), Capillary nail refill test abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Ejection fraction decreased (n/a - Fatal - **Results in Death**), Haematocrit increased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Hypovolaemia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Myocardial depression (n/a - Fatal - **Results in Death**), Presyncope (n/a - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Vasoplegia syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12598 | click or scan EU-EC-10009626373 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12599 | click or scan EU-EC-10009626352 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Duodenal ulcer haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock haemorrhagic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12600 | click or scan EU-EC-10009625666 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12601 | click or scan EU-EC-10009625624 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradykinesia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Unknown - ), Fall (n/a - Unknown - Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**), Near drowning (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**), Skin laceration (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12602 | click or scan EU-EC-10009625304 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12603 | click or scan EU-EC-10009625285 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12604 | click or scan EU-EC-10009625275 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12605 | click or scan EU-EC-10009625257 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bronchospasm (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12606 | click or scan EU-EC-10009625254 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12607 | click or scan EU-EC-10009625089 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Foaming at mouth (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12608 | click or scan EU-EC-10009624192 | | 2021-08-08 | Healthcare Professional | EEA | 65-85 Years | Female | Affect lability (95d - Fatal - **Results in Death**), Asthenia (95d - Fatal - **Results in Death**), Dysarthria (95d - Fatal - **Results in Death**), Gait disturbance (95d - Fatal - **Results in Death**), Rash (95d - Fatal - **Results in Death**), Rash pruritic (95d - Fatal - **Results in Death**), Visual impairment (95d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 12609 | click or scan EU-EC-10009623994 | | 2021-08-07 | Non Healthcare Professional | EEA | Not Specified | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 12610 | click or scan EU-EC-10009623981 | | 2021-08-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12611 | click or scan EU-EC-10009623854 | | 2021-08-07 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12612 | click or scan EU-EC-10009623617 | | 2021-08-07 | Healthcare Professional | EEA | 65-85 Years | Female | Agitation (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Choking (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Headache (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - ), Paralysis (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - 1mL - Intramuscular]) |
| 12613 | click or scan EU-EC-10009623269 | | 2021-08-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypertension (n/a - Unknown - **Results in Death**), Hypokinesia (n/a - Unknown - **Results in Death**), Paraesthesia (n/a - Unknown - **Results in Death**), Peripheral swelling (n/a - Unknown - **Results in Death**), Vision blurred (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12614 | click or scan EU-EC-10009623266 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Congestive cardiomyopathy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Heart valve incompetence (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Joint swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12615 | click or scan EU-EC-10009623194 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Not Recovered/Not Resolved - **Results in Death**), Hepatic failure (n/a - Not Recovered/Not Resolved - **Results in Death**), Ischaemic stroke (n/a - Recovered/Resolved - **Results in Death**), Pancreatitis (17d - Fatal - **Results in Death**), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12616 | click or scan EU-EC-10009623179 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriosclerosis coronary artery (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12617 | click or scan EU-EC-10009623172 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 12618 | click or scan EU-EC-10009622989 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Delusion (n/a - Not Recovered/Not Resolved - **Results in Death**), Mood altered (n/a - Not Recovered/Not Resolved - **Results in Death**), Suicidal ideation (n/a - Not Recovered/Not Resolved - **Results in Death**), Thinking abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12619 | click or scan EU-EC-10009622974 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Confusional state (n/a - Unknown - **Results in Death**), Crepitations (n/a - Unknown - **Results in Death**), Cystitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Unknown - **Results in Death**), Respiration abnormal (n/a - Unknown - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12620 | click or scan EU-EC-10009622970 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Death (5d - Fatal - **Results in Death**, Life Threatening), Illness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12621 | click or scan EU-EC-10009622770 | | 2021-08-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination site rash (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12622 | click or scan EU-EC-10009622765 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (12d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 12623 | click or scan EU-EC-10009622671 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 12624 | click or scan EU-EC-10009622664 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (5d - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Parenteral]) |
| 12625 | click or scan EU-EC-10009622614 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 12626 | click or scan EU-EC-10009622610 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic vein thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoperfusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Jugular vein thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Photophobia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Portal vein thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12627 | click or scan EU-EC-10009622485 | | 2021-08-07 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (1d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 12628 | click or scan EU-EC-10009622329 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 12629 | click or scan EU-EC-10009622222 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 12630 | click or scan EU-EC-10009622192 | | 2021-08-07 | Healthcare Professional | Non EEA | Not Specified | Female | Carotid artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic transformation stroke (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12631 | click or scan EU-EC-10009622180 | | 2021-08-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12632 | click or scan EU-EC-10009622174 | | 2021-08-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12633 | click or scan EU-EC-10009622121 | | 2021-08-07 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Erectile dysfunction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 12634 | click or scan EU-EC-10009621645 | | 2021-08-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12635 | click or scan EU-EC-10009620940 | | 2021-08-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12636 | click or scan EU-EC-10009620878 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**), Pulmonary fibrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 12637 | click or scan EU-EC-10009620740 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12638 | click or scan EU-EC-10009620717 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12639 | click or scan EU-EC-10009620697 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12640 | click or scan EU-EC-10009620686 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12641** | click or scan EU-EC-10009620667 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12642** | click or scan EU-EC-10009620659 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), Bradyphrenia (n/a - Unknown - ), Fatigue (1d - Fatal - **Results in Death**), Lethargy (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **12643** | click or scan EU-EC-10009620636 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (90min - Fatal - **Results in Death**, Other Medically Important Condition), Cold sweat (90min - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (90min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12644** | click or scan EU-EC-10009620616 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12645** | click or scan EU-EC-10009620604 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12646** | click or scan EU-EC-10009620593 | | 2021-08-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Coma (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12647** | click or scan EU-EC-10009620578 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12648** | click or scan EU-EC-10009620577 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (57h - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (9h - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12649** | click or scan EU-EC-10009620540 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (10d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**), Vaccination complication (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12650** | click or scan EU-EC-10009620288 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12651** | click or scan EU-EC-10009620102 | | 2021-08-06 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Abortion spontaneous (n/a - Fatal - **Results in Death**, Life Threatening, Congenital Anomaly, Other Medically Important Condition), Congenital anomaly (n/a - Fatal - **Results in Death**, Life Threatening, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **12652** | click or scan EU-EC-10009620016 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **12653** | click or scan EU-EC-10009619050 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12654** | click or scan EU-EC-10009618838 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Unknown - Other Medically Important Condition), Haematuria (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **12655** | click or scan EU-EC-10009618810 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12656** | click or scan EU-EC-10009618752 | | 2021-08-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Herpes zoster meningitis (n/a - Unknown - Other Medically Important Condition), Meningitis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12657** | click or scan EU-EC-10009618505 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cellulitis (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Pollakiuria (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12658** | click or scan EU-EC-10009618004 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Drug-induced liver injury (n/a - Fatal - **Results in Death**), Encephalitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), IPILIMUMAB [IPILIMUMAB] (S - Malignant melanoma - n/a - [n/a - n/a - Intravenous (not otherwise specified)]), NIVOLUMAB [NIVOLUMAB] (S - Malignant melanoma - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| **12659** | click or scan EU-EC-10009617819 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atelectasis (n/a - Unknown - ), Autoimmune haemolytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Diverticulum intestinal (n/a - Unknown - ), Haemolysis (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal cyst (n/a - Unknown - ), Spinal disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12660** | click or scan EU-EC-10009617713 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12661 | click or scan EU-EC-10009617712 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12662 | click or scan EU-EC-10009617440 | | 2021-08-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12663 | click or scan EU-EC-10009617303 | | 2021-08-06 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12664 | click or scan EU-EC-10009617199 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12665 | click or scan EU-EC-10009617115 | | 2021-08-06 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12666 | click or scan EU-EC-10009617007 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Insomnia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12667 | click or scan EU-EC-10009616963 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12668 | click or scan EU-EC-10009616747 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12669 | click or scan EU-EC-10009616443 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12670 | click or scan EU-EC-10009616392 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Cold sweat (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Emotional distress (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Feeling hot (n/a - Unknown - ), Feeling of body temperature change (n/a - Unknown - ), Micturition urgency (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12671 | click or scan EU-EC-10009616073 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Presyncope (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12672 | click or scan EU-EC-10009615999 | | 2021-08-06 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12673 | click or scan EU-EC-10009615996 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12674 | click or scan EU-EC-10009615995 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 12675 | click or scan EU-EC-10009615979 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Female | Pancreatitis acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12676 | click or scan EU-EC-10009615976 | | 2021-08-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12677 | click or scan EU-EC-10009615919 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12678 | click or scan EU-EC-10009615683 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12679 | click or scan EU-EC-10009615398 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Choking (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12680 | click or scan EU-EC-10009615212 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in jaw(n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12681 | click or scan EU-EC-10009615174 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12682 | click or scan EU-EC-10009614951 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Atrioventricular block complete (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12683 | click or scan EU-EC-10009614942 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Eye pruritus (n/a - Unknown - ), Fracture (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Paraesthesia oral (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12684 | click or scan EU-EC-10009614919 | | 2021-08-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Illness (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12685 | click or scan EU-EC-10009614649 | | 2021-08-06 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac disorder (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Medication error (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), NOT AVAILABLE [BNT 162] (S - Immunisation - n/a - [n/a - n/a - Unknown]), NOT AVAILABLE [MRNA 1273] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| 12686 | click or scan EU-EC-10009614414 | | 2021-08-06 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 12687 | click or scan EU-EC-10009613859 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12688 | click or scan EU-EC-10009613461 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neck mass (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12689** | click or scan EU-EC-10009612439 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **12690** | click or scan EU-EC-10009612402 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12691** | click or scan EU-EC-10009612121 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ascites (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritonitis bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **12692** | click or scan EU-EC-10009612085 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Retching (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **12693** | click or scan EU-EC-10009611866 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Aggression (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Hyperammonaemia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - ), Metabolic encephalopathy (n/a - Fatal - **Results in Death**), Pancytopenia (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - n/a - Dose increased - [n/a - n/a - n/a]), [TACROLIMUS] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]) |
| **12694** | click or scan EU-EC-10009611496 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **12695** | click or scan EU-EC-10009611438 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood culture negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abdomen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture urine negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ovarian vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine analysis normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12696** | click or scan EU-EC-10009611437 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **12697** | click or scan EU-EC-10009611379 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Male | Vascular stent thrombosis (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12698** | click or scan EU-EC-10009611016 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (14d - Fatal - **Results in Death**), Death (14d - Fatal - **Results in Death**), General physical health deterioration (14d - Fatal - **Results in Death**), Inflammation (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12699** | click or scan EU-EC-10009610937 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Cardiomyopathy (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12700** | click or scan EU-EC-10009610868 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Amylase increased (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Blood lactate dehydrogenase increased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest X-ray abnormal (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12701** | click or scan EU-EC-10009610720 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **12702** | click or scan EU-EC-10009610715 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12703** | click or scan EU-EC-10009610616 | | 2021-08-06 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**), Angina pectoris (1d - Fatal - **Results in Death**), Cardiovascular disorder (1d - Fatal - **Results in Death**), Coronary artery occlusion (1d - Fatal - **Results in Death**), Ejection fraction decreased (1d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), Fibrin D dimer increased (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Muscular weakness (1d - Fatal - **Results in Death**), Shock (1d - Fatal - **Results in Death**), Troponin increased (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12704** | click or scan EU-EC-10009610499 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **12705** | click or scan EU-EC-10009610313 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12706 | click or scan EU-EC-10009610288 | | 2021-08-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - ), Aortic thrombosis (n/a - Unknown - Life Threatening), Diarrhoea (n/a - Unknown - ), Haemorrhage (n/a - Unknown - Life Threatening), Infarction (n/a - Unknown - Life Threatening), Pain (n/a - Unknown - Life Threatening), Portal vein thrombosis (n/a - Unknown - Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12707 | click or scan EU-EC-10009610215 | | 2021-08-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Bleeding time prolonged (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12708 | click or scan EU-EC-10009609805 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12709 | click or scan EU-EC-10009609600 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diverticulitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Emphysema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12710 | click or scan EU-EC-10009609283 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Local reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12711 | click or scan EU-EC-10009609067 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetic coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12712 | click or scan EU-EC-10009608615 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea exertional (15d - Fatal - **Results in Death**), Gastrointestinal haemorrhage (15d - Fatal - **Results in Death**), Renal failure (15d - Fatal - **Results in Death**), Sepsis (15d - Fatal - **Results in Death**), Skin ulcer (15d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12713 | click or scan EU-EC-10009606215 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 12714 | click or scan EU-EC-10009607518 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12715 | click or scan EU-EC-10009607488 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12716 | click or scan EU-EC-10009607474 |  | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12717 | click or scan EU-EC-10009607458 |  | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12718 | click or scan EU-EC-10009607044 |  | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (n/a - Recovered/Resolved - Other Medically Important Condition), Electrocardiogram T wave inversion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved - ), Infection susceptibility increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Left ventricular hypertrophy (n/a - Not Recovered/Not Resolved - ), Pneumocystis jirovecii pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [PREDNISOLONE] (S - Prostate cancer - Not applicable - [n/a - 10mg - Oral]) |
| 12719 | click or scan EU-EC-10009607011 |  | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Contusion (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12720 | click or scan EU-EC-10009606691 |  | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 12721 | click or scan EU-EC-10009606486 |  | 2021-08-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (2d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12722 | click or scan EU-EC-10009605513 |  | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12723 | click or scan EU-EC-10009605148 |  | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Fatal - **Results in Death**), Gastrointestinal disorder (n/a - Fatal - **Results in Death**), Haemodynamic instability (n/a - Fatal - **Results in Death**), Liver injury (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Supraventricular tachycardia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12724 | click or scan EU-EC-10009604972 |  | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Eosinophilic bronchitis (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12725 | click or scan EU-EC-10009604935 |  | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12726 | click or scan EU-EC-10009604934 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12727 | click or scan EU-EC-10009604933 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematochezia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Large intestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Melaena (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myelodysplastic syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 12728 | click or scan EU-EC-10009604660 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12729 | click or scan EU-EC-10009604632 | | 2021-08-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Febrile convulsion (n/a - Fatal - **Results in Death**), Local reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12730 | click or scan EU-EC-10009604588 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic valve incompetence (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12731 | click or scan EU-EC-10009604265 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12732 | click or scan EU-EC-10009604250 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anxiety (n/a - Unknown - ), Completed suicide (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Mental disorder (n/a - Unknown - ), Neurosis (n/a - Unknown - ), Paranoia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12733 | click or scan EU-EC-10009603294 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 12734 | click or scan EU-EC-10009602942 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12735 | click or scan EU-EC-10009602568 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12736** | click or scan EU-EC-10009602497 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **12737** | click or scan EU-EC-10009602351 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **12738** | click or scan EU-EC-10009602278 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **12739** | click or scan EU-EC-10009602188 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [19d - 2 {DF} - Intramuscular]) |
| **12740** | click or scan EU-EC-10009602093 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12741** | click or scan EU-EC-10009601944 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse pressure decreased (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **12742** | click or scan EU-EC-10009601934 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12743** | click or scan EU-EC-10009601767 | | 2021-08-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **12744** | click or scan EU-EC-10009601602 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **12745** | click or scan EU-EC-10009601258 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12746 | click or scan EU-EC-10009601236 | | 2021-08-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fall (0d - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 12747 | click or scan EU-EC-10009601182 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Foaming at mouth (n/a - Unknown - ), SARS-CoV-2 antibody test positive (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12748 | click or scan EU-EC-10009601179 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nodule (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rales (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12749 | click or scan EU-EC-10009601166 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Unknown - ), Nausea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12750 | click or scan EU-EC-10009601150 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12751 | click or scan EU-EC-10009601146 | | 2021-08-05 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 12752 | click or scan EU-EC-10009601125 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12753 | click or scan EU-EC-10009601112 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Local reaction (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12754 | click or scan EU-EC-10009600918 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Throat tightness (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12755 | click or scan EU-EC-10009600867 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12756 | click or scan EU-EC-10009600802 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 12757 | click or scan EU-EC-10009600508 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 12758 | click or scan EU-EC-10009600438 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 12759 | click or scan EU-EC-10009599755 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arteriosclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), ECG signs of myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) DISPERSION FOR INJECTION [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| 12760 | click or scan EU-EC-10009599736 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 12761 | click or scan EU-EC-10009599629 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12762 | click or scan EU-EC-10009599616 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cough (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12763 | click or scan EU-EC-10009599577 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12764 | click or scan EU-EC-10009599565 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12765 | click or scan EU-EC-10009599556 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12766 | click or scan EU-EC-10009599497 | | 2021-08-05 | Healthcare Professional | EEA | Not Specified | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12767 | click or scan EU-EC-10009599251 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12768 | click or scan EU-EC-10009599101 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12769 | click or scan EU-EC-10009598994 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Local reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12770 | click or scan EU-EC-10009598988 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12771 | click or scan EU-EC-10009598983 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anuria (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Headache (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12772 | click or scan EU-EC-10009598885 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12773 | click or scan EU-EC-10009598839 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | Coagulopathy (5d - Fatal - **Results in Death**), Death (5d - Fatal - **Results in Death**), Haemorrhagic transformation stroke (5d - Fatal - **Results in Death**), Hemiplegia (5d - Fatal - **Results in Death**), Ischaemic stroke (5d - Fatal - **Results in Death**), Nerve compression (5d - Fatal - **Results in Death**), Nervous system disorder (5d - Fatal - **Results in Death**), Thrombocytopenia (5d - Fatal - **Results in Death**), Thrombosis (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12774 | click or scan EU-EC-10009598815 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12775 | click or scan EU-EC-10009598690 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 12776 | click or scan EU-EC-10009598653 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (2d - Fatal - **Results in Death**), Altered state of consciousness (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Hemiplegia (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**), International normalised ratio increased (2d - Fatal - **Results in Death**), Ischaemic stroke (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12777 | click or scan EU-EC-10009598647 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12778 | click or scan EU-EC-10009598505 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Coronary artery occlusion (n/a - Unknown - Other Medically Important Condition), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12779 | click or scan EU-EC-10009598500 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dry mouth (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12780 | click or scan EU-EC-10009598492 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12781 | click or scan EU-EC-10009598244 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Heart rate increased (13d - Fatal - **Results in Death**), Hemiparesis (13d - Fatal - **Results in Death**), Hypertension (13d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12782 | click or scan EU-EC-10009598216 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Erythema (n/a - Unknown - ), Exposure to SARS-CoV-2 (0d - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sudden unexplained death in epilepsy (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12783 | click or scan EU-EC-10009598176 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12784 | click or scan EU-EC-10009598164 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dyspnoea exertional (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12785 | click or scan EU-EC-10009598155 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Renal failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12786 | click or scan EU-EC-10009598041 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Blood alkaline phosphatase increased (n/a - Fatal - **Results in Death**), Burning sensation (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Cutaneous vasculitis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Skin disorder (n/a - Fatal - **Results in Death**), Spinal pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Urticaria (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12787 | click or scan EU-EC-10009597751 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Not Recovered/Not Resolved - ), Hypersensitivity (n/a - Unknown - ), Nausea (165min - Recovered/Resolved - ), Pneumonia (n/a - Recovering/Resolving - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12788 | click or scan EU-EC-10009597748 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bronchospasm (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12789 | click or scan EU-EC-10009597480 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12790 | click or scan EU-EC-10009597243 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), LIXIANA [EDOXABAN, EDOXABAN TOSYLATE] (S - Atrial fibrillation - Unknown - [n/a - 30mg - Oral]) |
| 12791 | click or scan EU-EC-10009597240 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12792 | click or scan EU-EC-10009597225 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12793 | click or scan EU-EC-10009597210 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12794 | click or scan EU-EC-10009597139 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12795 | click or scan EU-EC-10009597137 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12796 | click or scan EU-EC-10009597136 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12797 | click or scan EU-EC-10009597135 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12798 | click or scan EU-EC-10009597133 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12799 | click or scan EU-EC-10009597132 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12800 | click or scan EU-EC-10009597129 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12801 | click or scan EU-EC-10009597128 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12802 | click or scan EU-EC-10009597127 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12803 | click or scan EU-EC-10009597126 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12804 | click or scan EU-EC-10009597125 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12805** | click or scan EU-EC-10009597124 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12806** | click or scan EU-EC-10009597051 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12807** | click or scan EU-EC-10009597050 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12808** | click or scan EU-EC-10009597049 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12809** | click or scan EU-EC-10009597048 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12810** | click or scan EU-EC-10009596854 | | 2021-08-05 | Healthcare Professional | Non EEA | Not Specified | Male | Tremor (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12811** | click or scan EU-EC-10009596809 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **12812** | click or scan EU-EC-10009596796 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12813** | click or scan EU-EC-10009596759 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12814** | click or scan EU-EC-10009595962 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12815 | click or scan EU-EC-10009595960 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12816 | click or scan EU-EC-10009594708 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 12817 | click or scan EU-EC-10009593646 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12818 | click or scan EU-EC-10009593524 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 12819 | click or scan EU-EC-10009593428 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (1d - Unknown - ), Dizziness (1d - Unknown - ), Skin warm (1d - Unknown - ), Vaccination complication (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 12820 | click or scan EU-EC-10009593023 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12821 | click or scan EU-EC-10009592896 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12822 | click or scan EU-EC-10009592825 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12823 | click or scan EU-EC-10009592773 | | 2021-08-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12824 | click or scan EU-EC-10009592712 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12825 | click or scan EU-EC-10009592578 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12826 | click or scan EU-EC-10009592425 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Constipation (n/a - Unknown - ), Cystitis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12827 | click or scan EU-EC-10009592152 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Not Recovered/Not Resolved - ), Anosmia (n/a - Not Recovered/Not Resolved - ), COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - ), Pharyngeal swelling (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12828 | click or scan EU-EC-10009592018 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a - More in ICSR]) |
| 12829 | click or scan EU-EC-10009590991 | | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12830 | click or scan EU-EC-10009590950 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12831 | click or scan EU-EC-10009590934 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12832 | click or scan EU-EC-10009590924 | | 2021-08-04 | Non Healthcare Professional | EEA | Not Specified | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12833 | click or scan EU-EC-10009590479 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asphyxia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Cyanosis central (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Fall (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12834 | click or scan EU-EC-10009590239 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 2{DF} - Intramuscular]) |
| 12835 | click or scan EU-EC-10009590196 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12836 | click or scan EU-EC-10009590147 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Pyrexia (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 12837 | click or scan EU-EC-10009590055 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1 {DF} - Intramuscular]) |
| 12838 | click or scan EU-EC-10009590053 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (35d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [20d - 2 {DF} - Intramuscular]) |
| 12839 | click or scan EU-EC-10009589409 | | 2021-08-04 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12840 | click or scan EU-EC-10009589384 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bundle branch block right (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12841 | click or scan EU-EC-10009589376 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12842 | click or scan EU-EC-10009589350 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Unknown - ), Pulmonary fibrosis (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12843 | click or scan EU-EC-10009588922 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12844 | click or scan EU-EC-10009588723 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Local reaction (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Tenderness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12845 | click or scan EU-EC-10009588573 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12846** | click or scan EU-EC-10009588524 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12847** | click or scan EU-EC-10009588518 | | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12848** | click or scan EU-EC-10009588510 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abscess neck (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Head discomfort (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12849** | click or scan EU-EC-10009588500 | | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Meningoencephalitis herpetic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12850** | click or scan EU-EC-10009588342 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | Blood urine present (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Eschar (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12851** | click or scan EU-EC-10009588239 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (14d - Fatal - **Results in Death**, Life Threatening), Cardiovascular disorder (14d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (14d - Fatal - **Results in Death**, Life Threatening), N-terminal prohormone brain natriuretic peptide increased (14d - Fatal - **Results in Death**, Life Threatening), Respiratory disorder (14d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12852** | click or scan EU-EC-10009588097 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **12853** | click or scan EU-EC-10009588095 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12854** | click or scan EU-EC-10009588043 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12855** | click or scan EU-EC-10009587909 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Facial paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Slow response to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12856** | click or scan EU-EC-10009587790 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **12857** | click or scan EU-EC-10009587573 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **12858** | click or scan EU-EC-10009587571 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Autopsy (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12859** | click or scan EU-EC-10009587412 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **12860** | click or scan EU-EC-10009587205 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Haemoptysis (0d - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pneumonia bacterial (n/a - Fatal - **Results in Death**), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12861** | click or scan EU-EC-10009587126 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| **12862** | click or scan EU-EC-10009587052 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12863** | click or scan EU-EC-10009587048 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (11d - Fatal - **Results in Death**), Cerebral ischaemia (11d - Fatal - **Results in Death**), Hemiplegia (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **12864** | click or scan EU-EC-10009587036 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12865 | click or scan EU-EC-10009587021 |  | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 12866 | click or scan EU-EC-10009586986 |  | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12867 | click or scan EU-EC-10009586970 |  | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12868 | click or scan EU-EC-10009586968 |  | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 12869 | click or scan EU-EC-10009586866 |  | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12870 | click or scan EU-EC-10009586822 |  | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12871 | click or scan EU-EC-10009586498 |  | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 12872 | click or scan EU-EC-10009586443 |  | 2021-08-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**), Vaginal haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12873 | click or scan EU-EC-10009586001 |  | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12874 | click or scan EU-EC-10009585528 |  | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Drowning (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 12875 | click or scan EU-EC-10009585382 |  | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12876** | click or scan EU-EC-10009585019 |  | 2021-08-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ischaemia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12877** | click or scan EU-EC-10009584761 |  | 2021-08-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **12878** | click or scan EU-EC-10009584338 |  | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Incorrect route of product administration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Medication error (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| **12879** | click or scan EU-EC-10009584335 |  | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12880** | click or scan EU-EC-10009584334 |  | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12881** | click or scan EU-EC-10009584333 |  | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12882** | click or scan EU-EC-10009584332 |  | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12883** | click or scan EU-EC-10009584331 |  | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12884** | click or scan EU-EC-10009584330 |  | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12885** | click or scan EU-EC-10009584329 |  | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12886** | click or scan EU-EC-10009584328 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12887** | click or scan EU-EC-10009584327 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12888** | click or scan EU-EC-10009584326 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12889** | click or scan EU-EC-10009584248 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12890** | click or scan EU-EC-10009584247 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12891** | click or scan EU-EC-10009584246 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12892** | click or scan EU-EC-10009584245 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12893** | click or scan EU-EC-10009584244 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12894** | click or scan EU-EC-10009584243 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12895** | click or scan EU-EC-10009584242 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12896** | click or scan EU-EC-10009584241 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12897** | click or scan EU-EC-10009584240 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12898** | click or scan EU-EC-10009584239 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12899** | click or scan EU-EC-10009584238 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12900** | click or scan EU-EC-10009584237 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12901** | click or scan EU-EC-10009584236 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **12902** | click or scan EU-EC-10009584063 | | 2021-08-04 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12903** | click or scan EU-EC-10009583914 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Atrial flutter (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12904** | click or scan EU-EC-10009583133 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure increased (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **12905** | click or scan EU-EC-10009583004 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **12906** | click or scan EU-EC-10009581080 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12907 | click or scan EU-EC-10009582537 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12908 | click or scan EU-EC-10009582137 | | 2021-08-03 | Non Healthcare Professional | EEA | Not Specified | Male | COVID-19 (1d - Fatal - **Results in Death**) | [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 12909 | click or scan EU-EC-10009581859 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12910 | click or scan EU-EC-10009581424 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12911 | click or scan EU-EC-10009580541 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12912 | click or scan EU-EC-10009580436 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12913 | click or scan EU-EC-10009580238 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12914 | click or scan EU-EC-10009579767 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12915 | click or scan EU-EC-10009579666 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12916 | click or scan EU-EC-10009579181 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12917 | click or scan EU-EC-10009579178 | | 2021-08-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12918 | click or scan EU-EC-10009579175 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Constipation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dehydration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Enterobacter infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flushing (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12919 | click or scan EU-EC-10009579169 | | 2021-08-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12920 | click or scan EU-EC-10009579060 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 12921 | click or scan EU-EC-10009577919 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 12922 | click or scan EU-EC-10009577882 | | 2021-08-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12923 | click or scan EU-EC-10009577827 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12924 | click or scan EU-EC-10009577824 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 12925 | click or scan EU-EC-10009577817 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12926** | click or scan EU-EC-10009577772 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **12927** | click or scan EU-EC-10009577720 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Haemolytic anaemia (n/a - Fatal - **Results in Death**), Influenza like illness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **12928** | click or scan EU-EC-10009577716 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**), Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - n/a - Intramuscular]) |
| **12929** | click or scan EU-EC-10009577704 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **12930** | click or scan EU-EC-10009577678 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **12931** | click or scan EU-EC-10009577675 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12932** | click or scan EU-EC-10009577643 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **12933** | click or scan EU-EC-10009577440 | | 2021-08-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Unknown - Other Medically Important Condition), Hip fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **12934** | click or scan EU-EC-10009577140 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **12935** | click or scan EU-EC-10009576724 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site haemorrhage (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **12936** | click or scan EU-EC-10009576190 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Agonal rhythm (62d - Fatal - **Results in Death**), Asthenia (62d - Fatal - **Results in Death**), Cardiac arrest (62d - Fatal - **Results in Death**), Death (62d - Fatal - **Results in Death**), Dyspnoea (62d - Fatal - **Results in Death**), Endotracheal intubation (62d - Fatal - **Results in Death**), Feeling cold (62d - Fatal - **Results in Death**), Oedema peripheral (62d - Fatal - **Results in Death**), Oxygen saturation decreased (62d - Fatal - **Results in Death**), Rash macular (62d - Fatal - **Results in Death**), Respiratory disorder (62d - Fatal - **Results in Death**), Syncope (62d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **12937** | click or scan EU-EC-10009576077 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12938** | click or scan EU-EC-10009576063 | | 2021-08-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12939** | click or scan EU-EC-10009576056 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bone contusion (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Monoplegia (n/a - Fatal - **Results in Death**), Musculoskeletal chest pain (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular]) |
| **12940** | click or scan EU-EC-10009576054 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cold sweat (n/a - Unknown - ), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory rate increased (n/a - Unknown - ), Restlessness (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **12941** | click or scan EU-EC-10009576049 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12942** | click or scan EU-EC-10009576036 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12943** | click or scan EU-EC-10009576034 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **12944** | click or scan EU-EC-10009576023 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **12945** | click or scan EU-EC-10009575912 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agonal respiration (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Heart rate decreased (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12946 | click or scan EU-EC-10009575896 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure fluctuation (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mouth breathing (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pupillary reflex impaired (n/a - Unknown - Other Medically Important Condition), Pupils unequal (n/a - Unknown - Other Medically Important Condition), Pyelonephritis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**), Skin discolouration (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12947 | click or scan EU-EC-10009575622 | | 2021-08-03 | Healthcare Professional | EEA | Not Specified | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12948 | click or scan EU-EC-10009575561 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 12949 | click or scan EU-EC-10009575524 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12950 | click or scan EU-EC-10009575376 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 12951 | click or scan EU-EC-10009574769 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Organising pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 12952 | click or scan EU-EC-10009574571 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Posture abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12953 | click or scan EU-EC-10009574565 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12954 | click or scan EU-EC-10009574507 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12955 | click or scan EU-EC-10009574332 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12956 | click or scan EU-EC-10009574237 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12957 | click or scan EU-EC-10009574232 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 12958 | click or scan EU-EC-10009573773 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12959 | click or scan EU-EC-10009573654 | | 2021-08-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Body mass index abnormal (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12960 | click or scan EU-EC-10009573640 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cold sweat (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12961 | click or scan EU-EC-10009573267 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Constipation (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12962 | click or scan EU-EC-10009573261 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (n/a - Fatal - **Results in Death**, Life Threatening), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Crepitations (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening), Food refusal (n/a - Fatal - **Results in Death**, Life Threatening), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Tachycardia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12963 | click or scan EU-EC-10009573141 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12964 | click or scan EU-EC-10009573029 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 12965 | click or scan EU-EC-10009572379 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 12966 | click or scan EU-EC-10009572186 |  | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (n/a - Not Recovered/Not Resolved - ), Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) - DISPERSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 12967 | click or scan EU-EC-10009572090 |  | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Heat illness (n/a - Unknown - ), Left ventricular failure (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12968 | click or scan EU-EC-10009571976 |  | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12969 | click or scan EU-EC-10009571702 |  | 2021-08-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12970 | click or scan EU-EC-10009571596 |  | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute abdomen (n/a - Fatal - **Results in Death**), Chest discomfort (1d - Recovered/Resolved - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Haematochezia (n/a - Unknown - Other Medically Important Condition), Mesenteric arterial occlusion (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 12971 | click or scan EU-EC-10009571446 |  | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 12972 | click or scan EU-EC-10009571438 |  | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Feeling hot (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12973 | click or scan EU-EC-10009571434 |  | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12974 | click or scan EU-EC-10009571395 |  | 2021-08-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac valve disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12975 | click or scan EU-EC-10009571324 |  | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Carotid artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **12976** | click or scan EU-EC-10009571299 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cheyne-Stokes respiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **12977** | click or scan EU-EC-10009570527 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **12978** | click or scan EU-EC-10009570497 | | 2021-08-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |
| **12979** | click or scan EU-EC-10009570496 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular]) |
| **12980** | click or scan EU-EC-10009569569 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **12981** | click or scan EU-EC-10009569147 | | 2021-08-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **12982** | click or scan EU-EC-10009568481 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **12983** | click or scan EU-EC-10009567851 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **12984** | click or scan EU-EC-10009567335 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12985 | click or scan EU-EC-10009567161 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12986 | click or scan EU-EC-10009566801 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure like phenomena (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 12987 | click or scan EU-EC-10009566703 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bronchiectasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mycobacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pseudomonas infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 12988 | click or scan EU-EC-10009566628 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cellulitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling hot (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral circulatory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 12989 | click or scan EU-EC-10009566566 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 12990 | click or scan EU-EC-10009566476 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 12991 | click or scan EU-EC-10009566437 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12992 | click or scan EU-EC-10009566332 | | 2021-08-02 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 12993 | click or scan EU-EC-10009566317 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 12994 | click or scan EU-EC-10009565780 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Back pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dysstasia (n/a - Unknown - ), Infection (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12995 | click or scan EU-EC-10009565509 | | 2021-08-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Tongue oedema (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 12996 | click or scan EU-EC-10009565223 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (3d - Recovered/Resolved - ), COVID-19 (18d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cavernous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mucormycosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain (2d - Recovered/Resolved - ), Pulmonary fibrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 12997 | click or scan EU-EC-10009565103 | | 2021-08-02 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Venous oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 12998 | click or scan EU-EC-10009565076 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 12999 | click or scan EU-EC-10009565064 | | 2021-08-02 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cough (9d - Fatal - **Results in Death**), Dyspnoea (5d - Fatal - **Results in Death**), Pneumonia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13000 | click or scan EU-EC-10009564668 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (18d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (18d - Fatal - **Results in Death**), Pain (18d - Fatal - **Results in Death**), Pain in extremity (18d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13001 | click or scan EU-EC-10009564637 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aggression (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13002 | click or scan EU-EC-10009564198 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13003 | click or scan EU-EC-10009564173 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Respiratory rate decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13004 | click or scan EU-EC-10009564042 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 13005 | click or scan EU-EC-10009563935 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Chest injury (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13006 | click or scan EU-EC-10009563857 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dementia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 13007 | click or scan EU-EC-10009563799 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13008 | click or scan EU-EC-10009563665 | | 2021-08-02 | Non Healthcare Professional | EEA | Not Specified | Male | Bundle branch block bilateral (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma hepatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatorenal syndrome (n/a - Unknown - Other Medically Important Condition), Hyperuricaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritonitis bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Varices oesophageal (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13009 | click or scan EU-EC-10009563652 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adrenal insufficiency (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13010 | click or scan EU-EC-10009563537 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agitation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose increased (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling of body temperature change (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hallucination (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 13011 | click or scan EU-EC-10009563433 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13012 | click or scan EU-EC-10009563335 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Renal failure (69d - Fatal - **Results in Death**, Other Medically Important Condition), Renal tubular necrosis (69d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13013** | click or scan EU-EC-10009562983 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chills (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **13014** | click or scan EU-EC-10009562930 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial aneurysm (50d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **13015** | click or scan EU-EC-10009562770 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pollakiuria (n/a - Fatal - **Results in Death**), Toothache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13016** | click or scan EU-EC-10009562752 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Biliary sepsis (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |
| **13017** | click or scan EU-EC-10009562624 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13018** | click or scan EU-EC-10009562492 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Body temperature increased (3d - Recovered/Resolved - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tonsillar hypertrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13019** | click or scan EU-EC-10009562434 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13020** | click or scan EU-EC-10009562391 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13021** | click or scan EU-EC-10009561754 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **13022** | click or scan EU-EC-10009561561 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13023 | click or scan EU-EC-10009561197 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Female | Cavernous sinus thrombosis (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13024 | click or scan EU-EC-10009561153 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13025 | click or scan EU-EC-10009560647 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13026 | click or scan EU-EC-10009560637 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13027 | click or scan EU-EC-10009560630 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), White blood cell count increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13028 | click or scan EU-EC-10009560535 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13029 | click or scan EU-EC-10009560534 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Aortic thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Intestinal ischaemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Neutrophilia (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet anisocytosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Splenic infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Splenic thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis mesenteric vessel (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13030 | click or scan EU-EC-10009560468 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13031 | click or scan EU-EC-10009559971 | | 2021-08-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13032** | click or scan EU-EC-10009559933 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (8d - Unknown - ), Asthenia (8d - Not Recovered/Not Resolved - ), Atrial fibrillation (7d - Not Recovered/Not Resolved - ), COVID-19 pneumonia (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (8d - Unknown - ), Headache (9d - Unknown - ), Hypotension (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [5s - 1 {DF} - Intramuscular]) |
| **13033** | click or scan EU-EC-10009559778 | | 2021-08-02 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Cardiac failure chronic (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13034** | click or scan EU-EC-10009559507 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **13035** | click or scan EU-EC-10009558818 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral artery embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13036** | click or scan EU-EC-10009558727 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13037** | click or scan EU-EC-10009558629 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **13038** | click or scan EU-EC-10009558474 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure increased (n/a - Unknown - ), Cardiac hypertrophy (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vascular occlusion (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13039** | click or scan EU-EC-10009558467 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Endocarditis noninfective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Intracardiac thrombus (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Myocardial injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13040** | click or scan EU-EC-10009558149 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Dehydration (n/a - Unknown - Other Medically Important Condition), Visual acuity reduced (2d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13041** | click or scan EU-EC-10009557750 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13042** | click or scan EU-EC-10009557714 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13043** | click or scan EU-EC-10009557713 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13044** | click or scan EU-EC-10009556468 | | 2021-07-31 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| **13045** | click or scan EU-EC-10009555729 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **13046** | click or scan EU-EC-10009555626 | | 2021-07-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**), Thrombosis (n/a - Recovering/Resolving - **Results in Death**), Vaccination failure (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **13047** | click or scan EU-EC-10009555608 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cold sweat (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Food refusal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maximum heart rate increased (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13048** | click or scan EU-EC-10009555604 | | 2021-07-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decubitus ulcer (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammatory marker increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination error (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13049** | click or scan EU-EC-10009555581 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Blood lactic acid increased (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Brain hypoxia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Ischaemia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vasculitis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13050** | click or scan EU-EC-10009555408 | | 2021-07-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute left ventricular failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13051** | click or scan EU-EC-10009555405 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Giant cell arteritis (n/a - Unknown - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **13052** | click or scan EU-EC-10009555383 | | 2021-07-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Folate deficiency (n/a - Unknown - **Results in Death**), Haemoptysis (n/a - Not Recovered/Not Resolved - **Results in Death**), Haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**), Iron deficiency (n/a - Unknown - **Results in Death**), Normocytic anaemia (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **13053** | click or scan EU-EC-10009555329 | | 2021-07-31 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **13054** | click or scan EU-EC-10009555260 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Epistaxis (n/a - Not Recovered/Not Resolved - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **13055** | click or scan EU-EC-10009555201 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood urine (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Device occlusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage urinary tract (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **13056** | click or scan EU-EC-10009555060 | | 2021-07-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening), Pneumonia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13057** | click or scan EU-EC-10009555059 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Aphasia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Brain injury (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Disorientation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial pressure increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupillary light reflex tests abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13058** | click or scan EU-EC-10009555047 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **13059** | click or scan EU-EC-10009555046 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**), Activated partial thromboplastin time prolonged (n/a - Unknown - **Results in Death**), Embolism (n/a - Unknown - **Results in Death**), Intestinal ischaemia (n/a - Unknown - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **13060** | click or scan EU-EC-10009554961 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13061** | click or scan EU-EC-10009554960 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Unknown - **Results in Death**), Influenza like illness (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **13062** | click or scan EU-EC-10009554606 | | 2021-07-31 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **13063** | click or scan EU-EC-10009554425 | | 2021-07-31 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Anxiety (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (23d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Incontinence (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13064** | click or scan EU-EC-10009554418 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Hyperhidrosis (n/a - Unknown - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - **Results in Death**), Sleep disorder (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13065** | click or scan EU-EC-10009554396 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Unknown - **Results in Death**), Cardiac failure congestive (n/a - Unknown - **Results in Death**), Dizziness (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **13066** | click or scan EU-EC-10009554390 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13067** | click or scan EU-EC-10009553829 | | 2021-07-31 | Healthcare Professional | EEA | 65-85 Years | Male | Ascites (86d - Fatal - **Results in Death**), Colon cancer (86d - Fatal - **Results in Death**), Lymphadenopathy (86d - Fatal - **Results in Death**), Metastases to liver (86d - Fatal - **Results in Death**), Metastases to lung (86d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .5mL - Intramuscular]) |
| **13068** | click or scan EU-EC-10009553763 | | 2021-07-31 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory failure (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **13069** | click or scan EU-EC-10009553745 | | 2021-07-31 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13070** | click or scan EU-EC-10009552923 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **13071** | click or scan EU-EC-10009552869 | | 2021-07-31 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **13072** | click or scan EU-EC-10009552322 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13073** | click or scan EU-EC-10009552277 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13074** | click or scan EU-EC-10009551698 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Angioimmunoblastic T-cell lymphoma (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tubulointerstitial nephritis (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [2d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13075 | click or scan EU-EC-10009551640 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Female | Capillary leak syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13076 | click or scan EU-EC-10009551392 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13077 | click or scan EU-EC-10009551194 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13078 | click or scan EU-EC-10009550584 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13079 | click or scan EU-EC-10009550522 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Catastrophic reaction (2d - Fatal - **Results in Death**), Cerebrovascular accident (2d - Fatal - **Results in Death**, Other Medically Important Condition), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13080 | click or scan EU-EC-10009550235 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13081 | click or scan EU-EC-10009549456 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Oedema (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13082 | click or scan EU-EC-10009549444 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neck mass (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13083 | click or scan EU-EC-10009549392 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Injection site pain (2d - Recovered/Resolved - ), Injection site pruritus (2d - Recovered/Resolved - ), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13084 | click or scan EU-EC-10009549354 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Malaise (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13085 | click or scan EU-EC-10009549246 |  | 2021-07-30 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal distension (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed mood (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Non-Hodgkin's lymphoma (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13086 | click or scan EU-EC-10009548680 |  | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Venous thrombosis limb (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13087 | click or scan EU-EC-10009548347 |  | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dysuria (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13088 | click or scan EU-EC-10009548241 |  | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13089 | click or scan EU-EC-10009548173 |  | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13090 | click or scan EU-EC-10009547783 |  | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13091 | click or scan EU-EC-10009547512 |  | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13092 | click or scan EU-EC-10009547487 |  | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13093 | click or scan EU-EC-10009547454 |  | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13094 | click or scan EU-EC-10009547414 |  | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13095 | click or scan EU-EC-10009547286 | | 2021-07-30 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13096 | click or scan EU-EC-10009547001 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13097 | click or scan EU-EC-10009546788 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Musculoskeletal discomfort (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13098 | click or scan EU-EC-10009546759 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13099 | click or scan EU-EC-10009546137 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13100 | click or scan EU-EC-10009546136 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Near drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13101 | click or scan EU-EC-10009546071 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Foaming at mouth (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13102 | click or scan EU-EC-10009545930 | | 2021-07-30 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13103 | click or scan EU-EC-10009545767 | | 2021-07-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Unknown - Other Medically Important Condition), Congestive hepatopathy (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Productive cough (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13104 | click or scan EU-EC-10009545667 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13105 | click or scan EU-EC-10009545572 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13106 | click or scan EU-EC-10009545479 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13107 | click or scan EU-EC-10009544851 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Female | Left ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13108 | click or scan EU-EC-10009544795 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - ), Circulatory collapse (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13109 | click or scan EU-EC-10009544209 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13110 | click or scan EU-EC-10009544170 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13111 | click or scan EU-EC-10009544138 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13112 | click or scan EU-EC-10009544103 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13113 | click or scan EU-EC-10009544100 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Cardiac arrest (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13114 | click or scan EU-EC-10009544097 | | 2021-07-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Capillary leak syndrome (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Taste disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13115 | click or scan EU-EC-10009544094 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13116 | click or scan EU-EC-10009543811 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), COVID-19 immunisation (n/a - Fatal - **Results in Death**), Dysgeusia (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 13117 | click or scan EU-EC-10009543795 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hypopnoea (n/a - Fatal - **Results in Death**), Increased upper airway secretion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13118 | click or scan EU-EC-10009543540 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (11h - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13119 | click or scan EU-EC-10009541941 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13120 | click or scan EU-EC-10009541398 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13121 | click or scan EU-EC-10009541252 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - ), Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Delirium (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Unknown - ), Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Ventricular extrasystoles (n/a - Unknown - ), White blood cell count decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13122 | click or scan EU-EC-10009540998 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13123 | click or scan EU-EC-10009540761 |  | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13124 | click or scan EU-EC-10009540464 |  | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13125 | click or scan EU-EC-10009540115 |  | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Leukaemia (n/a - Fatal - **Results in Death**), Motor dysfunction (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13126 | click or scan EU-EC-10009539502 |  | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13127 | click or scan EU-EC-10009612908 |  | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Anti-neutrophil cytoplasmic antibody positive vasculitis (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood disorder (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypophagia (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 13128 | click or scan EU-EC-10009539030 |  | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13129 | click or scan EU-EC-10009538901 |  | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13130 | click or scan EU-EC-10009538127 |  | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Male | Autoimmune hepatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jaundice (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13131 | click or scan EU-EC-10009538086 |  | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13132 | click or scan EU-EC-10009538047 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13133 | click or scan EU-EC-10009537965 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subclavian vein thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 13134 | click or scan EU-EC-10009537818 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain upper (56d - Fatal - **Results in Death**, Life Threatening, Disabling), Back pain (56d - Fatal - **Results in Death**, Life Threatening, Disabling), Blindness (56d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pain (56d - Fatal - **Results in Death**, Life Threatening, Disabling), Plasma cell myeloma (56d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13135 | click or scan EU-EC-10009537803 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Female | Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13136 | click or scan EU-EC-10009537679 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13137 | click or scan EU-EC-10009537575 | | 2021-07-29 | Non Healthcare Professional | Non EEA | Not Specified | Female | Acute promyelocytic leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13138 | click or scan EU-EC-10009537415 | | 2021-07-29 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Foetal hypokinesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Low birth weight baby (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Stillbirth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Transplacental]) |
| 13139 | click or scan EU-EC-10009537405 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Incorrect route of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 13140 | click or scan EU-EC-10009536800 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13141 | click or scan EU-EC-10009536546 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myeloid leukaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13142 | click or scan EU-EC-10009536428 |  | 2021-07-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Gait disturbance (n/a - Unknown - **Results in Death**), Haematoma (n/a - Unknown - **Results in Death**), Hypersomnia (n/a - Unknown - **Results in Death**), Nervousness (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13143 | click or scan EU-EC-10009536337 |  | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13144 | click or scan EU-EC-10009536193 |  | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13145 | click or scan EU-EC-10009536115 |  | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Poor quality product administered (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13146 | click or scan EU-EC-10009536099 |  | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13147 | click or scan EU-EC-10009535917 |  | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 13148 | click or scan EU-EC-10009535755 |  | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Constipation (n/a - Unknown - ), Cough (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dysphonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Unknown - ), Pain (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - ), Sensation of foreign body (n/a - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13149 | click or scan EU-EC-10009535654 |  | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (12d - Fatal - **Results in Death**), Fatigue (12d - Fatal - **Results in Death**), Headache (12d - Fatal - **Results in Death**), Vaccine positive rechallenge (12d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13150 | click or scan EU-EC-10009535576 |  | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac hypertrophy (1d - Fatal - **Results in Death**), Deep vein thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Prostate cancer (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13151 | click or scan EU-EC-10009535296 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (S - Atrial fibrillation - Not applicable - [n/a - 20mg - n/a]) |
| 13152 | click or scan EU-EC-10009535288 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), XARELTO [RIVAROXABAN] (S - Atrial fibrillation - Not applicable - [n/a - 20mg - n/a]) |
| 13153 | click or scan EU-EC-10009535248 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13154 | click or scan EU-EC-10009534910 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13155 | click or scan EU-EC-10009534758 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 13156 | click or scan EU-EC-10009534616 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13157 | click or scan EU-EC-10009534609 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13158 | click or scan EU-EC-10009534607 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13159 | click or scan EU-EC-10009534601 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13160 | click or scan EU-EC-10009534476 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13161 | click or scan EU-EC-10009534389 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13162 | click or scan EU-EC-10009534103 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13163 | click or scan EU-EC-10009534090 | | 2021-07-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13164 | click or scan EU-EC-10009533788 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Myositis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Spontaneous haematoma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13165 | click or scan EU-EC-10009533760 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Angioedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13166 | click or scan EU-EC-10009533753 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13167 | click or scan EU-EC-10009533719 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13168 | click or scan EU-EC-10009533718 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 13169 | click or scan EU-EC-10009533717 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 13170 | click or scan EU-EC-10009533709 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Troponin abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13171 | click or scan EU-EC-10009533653 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13172 | click or scan EU-EC-10009533648 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Pulseless electrical activity (1d - Fatal - **Results in Death**), Ventricular fibrillation (1d - Not Recovered/Not Resolved - Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13173 | click or scan EU-EC-10009533625 | | 2021-07-29 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Bradycardia foetal (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 13174 | click or scan EU-EC-10009533595 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suicide attempt (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13175 | click or scan EU-EC-10009533565 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13176 | click or scan EU-EC-10009533412 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Poor quality product administered (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13177 | click or scan EU-EC-10009532514 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Erythema (3d - Fatal - **Results in Death**), Nodule (3d - Fatal - **Results in Death**), Peripheral swelling (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13178 | click or scan EU-EC-10009532011 | | 2021-07-29 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13179 | click or scan EU-EC-10009531981 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pancreatitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13180 | click or scan EU-EC-10009531962 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13181 | click or scan EU-EC-10009531823 | | 2021-07-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13182 | click or scan EU-EC-10009531724 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13183 | click or scan EU-EC-10009531669 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13184 | click or scan EU-EC-10009531537 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13185 | click or scan EU-EC-10009531444 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Contusion (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition), Vascular dementia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13186 | click or scan EU-EC-10009531246 | | 2021-07-29 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13187 | click or scan EU-EC-10009530470 | | 2021-07-29 | Healthcare Professional | EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13188 | click or scan EU-EC-10009530376 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Autoimmune haemolytic anaemia (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenectomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13189 | click or scan EU-EC-10009530224 | | 2021-07-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (2d - Fatal - **Results in Death**), Chills (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**), Hypoaesthesia (2d - Fatal - **Results in Death**), Hypopnoea (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 13190 | click or scan EU-EC-10009529859 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13191 | click or scan EU-EC-10009529847 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13192 | click or scan EU-EC-10009529831 | | 2021-07-29 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13193 | click or scan EU-EC-10009529828 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13194 | click or scan EU-EC-10009529772 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13195 | click or scan EU-EC-10009529646 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13196 | click or scan EU-EC-10009528731 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13197 | click or scan EU-EC-10009528674 | | 2021-07-29 | Healthcare Professional | EEA | Not Specified | Female | Axillary vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13198 | click or scan EU-EC-10009528415 | | 2021-07-29 | Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13199 | click or scan EU-EC-10009528277 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse reaction (n/a - Unknown - ), Aortic valve disease (n/a - Unknown - ), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Cyanosis (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Illness (n/a - Unknown - ), Insomnia (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - ), Pallor (n/a - Unknown - ), Paradoxical drug reaction (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Pulmonary mass (n/a - Unknown - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - ), Suicidal ideation (n/a - Unknown - Other Medically Important Condition), Vaccination site erythema (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ), Vasodilatation (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13200 | click or scan EU-EC-10009528259 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Flank pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Urine copper (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13201 | click or scan EU-EC-10009528228 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Connective tissue disorder (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhagic disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13202 | click or scan EU-EC-10009528207 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia bacterial (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13203 | click or scan EU-EC-10009527573 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13204 | click or scan EU-EC-10009526900 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Unknown - ), COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13205 | click or scan EU-EC-10009526876 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cognitive disorder (n/a - Fatal - **Results in Death**), Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Lethargy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13206 | click or scan EU-EC-10009526015 | | 2021-07-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13207 | click or scan EU-EC-10009525478 | | 2021-07-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neuromyelitis optica spectrum disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13208 | click or scan EU-EC-10009524720 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13209 | click or scan EU-EC-10009524690 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 13210 | click or scan EU-EC-10009524335 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13211** | click or scan EU-EC-10009524319 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | ELIQUIS [APIXABAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (S - n/a - n/a - [n/a - n/a - n/a]), [BENSERAZIDE, LEVODOPA] (S - n/a - n/a - [n/a - n/a - n/a]), [BIPERIDEN, BIPERIDEN HYDROCHLORIDE, BIPERIDEN LACTATE] (S - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (S - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (S - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **13212** | click or scan EU-EC-10009524310 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcal sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13213** | click or scan EU-EC-10009524268 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13214** | click or scan EU-EC-10009524264 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13215** | click or scan EU-EC-10009524259 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anuria (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13216** | click or scan EU-EC-10009524256 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13217** | click or scan EU-EC-10009524240 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13218** | click or scan EU-EC-10009524232 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13219 | click or scan EU-EC-10009524231 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13220 | click or scan EU-EC-10009524202 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13221 | click or scan EU-EC-10009524190 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13222 | click or scan EU-EC-10009523869 | | 2021-07-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate irregular (1d - Fatal - **Results in Death**), Memory impairment (1d - Fatal - **Results in Death**), Sleep apnoea syndrome (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 13223 | click or scan EU-EC-10009523797 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13224 | click or scan EU-EC-10009523784 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13225 | click or scan EU-EC-10009523624 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 13226 | click or scan EU-EC-10009523566 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13227 | click or scan EU-EC-10009523499 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13228 | click or scan EU-EC-10009523490 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Female | Brain injury (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13229** | click or scan EU-EC-10009523460 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13230** | click or scan EU-EC-10009522992 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Unknown - ), Limb discomfort (n/a - Unknown - ), Nightmare (n/a - Unknown - ), Oedema (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13231** | click or scan EU-EC-10009522895 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Autoimmune haemolytic anaemia (8d - Fatal - **Results in Death**), Pulmonary embolism (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13232** | click or scan EU-EC-10009522781 | | 2021-07-28 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Abortion induced (n/a - Fatal - **Results in Death**, Congenital Anomaly), Congenital nose malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Cytogenetic abnormality (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Limb malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Multiple congenital abnormalities (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| **13233** | click or scan EU-EC-10009522720 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Paralysis (7d - Fatal - **Results in Death**), Respiratory failure (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13234** | click or scan EU-EC-10009522634 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13235** | click or scan EU-EC-10009522518 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Crush syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13236** | click or scan EU-EC-10009522508 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13237** | click or scan EU-EC-10009522403 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **13238** | click or scan EU-EC-10009522286 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13239 | click or scan EU-EC-10009522245 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Female | Pemphigoid (5mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 13240 | click or scan EU-EC-10009522201 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13241 | click or scan EU-EC-10009522180 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Alveolitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Autoimmune disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13242 | click or scan EU-EC-10009522176 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13243 | click or scan EU-EC-10009521978 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 13244 | click or scan EU-EC-10009521945 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13245 | click or scan EU-EC-10009521901 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory distress syndrome (23d - Fatal - **Results in Death**), Lung infiltration (23d - Fatal - **Results in Death**), Lung transplant rejection (23d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 13246 | click or scan EU-EC-10009521797 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Acute left ventricular failure (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute myocardial infarction (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13247 | click or scan EU-EC-10009521777 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13248 | click or scan EU-EC-10009521748 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13249** | click or scan EU-EC-10009521672 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13250** | click or scan EU-EC-10009521647 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13251** | click or scan EU-EC-10009521636 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13252** | click or scan EU-EC-10009521609 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Influenza like illness (2d - Fatal - **Results in Death**), Myalgia (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13253** | click or scan EU-EC-10009521292 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **13254** | click or scan EU-EC-10009521250 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13255** | click or scan EU-EC-10009521207 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Nausea (0d - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13256** | click or scan EU-EC-10009521155 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **13257** | click or scan EU-EC-10009521107 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **13258** | click or scan EU-EC-10009520936 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13259 | click or scan EU-EC-10009520928 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13260 | click or scan EU-EC-10009520818 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Male | Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13261 | click or scan EU-EC-10009520704 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13262 | click or scan EU-EC-10009520483 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13263 | click or scan EU-EC-10009520360 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13264 | click or scan EU-EC-10009520044 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Influenza (n/a - Not Recovered/Not Resolved - ), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13265 | click or scan EU-EC-10009519982 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Gastric haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13266 | click or scan EU-EC-10009519922 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13267 | click or scan EU-EC-10009519919 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13268 | click or scan EU-EC-10009519892 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Resuscitation (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13269 | click or scan EU-EC-10009519867 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13270 | click or scan EU-EC-10009519866 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13271 | click or scan EU-EC-10009519846 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Nasopharyngitis (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13272 | click or scan EU-EC-10009519751 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13273 | click or scan EU-EC-10009519684 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13274 | click or scan EU-EC-10009519575 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pancytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13275 | click or scan EU-EC-10009519563 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13276 | click or scan EU-EC-10009519331 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13277 | click or scan EU-EC-10009519195 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13278 | click or scan EU-EC-10009519143 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13279 | click or scan EU-EC-10009519140 | | 2021-07-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pancreatic carcinoma (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13280 | click or scan EU-EC-10009519113 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Epilepsy (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13281 | click or scan EU-EC-10009519110 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13282 | click or scan EU-EC-10009518790 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13283 | click or scan EU-EC-10009518786 | | 2021-07-28 | Non Healthcare Professional | EEA | Not Specified | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Circulatory collapse (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Peripheral vascular disorder (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13284 | click or scan EU-EC-10009518783 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13285 | click or scan EU-EC-10009518671 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13286 | click or scan EU-EC-10009518621 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13287 | click or scan EU-EC-10009518381 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Septic shock (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13288 | click or scan EU-EC-10009518312 | | 2021-07-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13289 | click or scan EU-EC-10009518262 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (2d - Fatal - **Results in Death**), Myocardial ischaemia (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13290 | click or scan EU-EC-10009518243 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13291 | click or scan EU-EC-10009518114 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13292 | click or scan EU-EC-10009518108 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13293 | click or scan EU-EC-10009518041 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiovascular disorder (3d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Fatigue (3d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13294 | click or scan EU-EC-10009518038 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13295 | click or scan EU-EC-10009517977 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13296 | click or scan EU-EC-10009517360 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13297 | click or scan EU-EC-10009516936 | | 2021-07-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Hyperventilation (n/a - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| 13298 | click or scan EU-EC-10009516608 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13299 | click or scan EU-EC-10009516535 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain stem infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13300 | click or scan EU-EC-10009516050 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13301 | click or scan EU-EC-10009516039 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Hypereosinophilic syndrome (n/a - Fatal - **Results in Death**), Lung carcinoma cell type unspecified stage 0 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13302 | click or scan EU-EC-10009516030 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13303 | click or scan EU-EC-10009515766 | | 2021-07-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13304 | click or scan EU-EC-10009515739 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Body temperature increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13305 | click or scan EU-EC-10009515737 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Malaise (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Right atrial enlargement (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13306 | click or scan EU-EC-10009515720 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13307 | click or scan EU-EC-10009515582 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13308 | click or scan EU-EC-10009515573 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13309 | click or scan EU-EC-10009515565 | | 2021-07-28 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13310 | click or scan EU-EC-10009515496 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13311 | click or scan EU-EC-10009515423 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13312 | click or scan EU-EC-10009515396 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13313 | click or scan EU-EC-10009515389 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13314 | click or scan EU-EC-10009515360 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13315 | click or scan EU-EC-10009515248 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13316 | click or scan EU-EC-10009515229 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Extrasystoles (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13317 | click or scan EU-EC-10009515228 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (19d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13318 | click or scan EU-EC-10009514835 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13319 | click or scan EU-EC-10009514645 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiomyopathy (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| 13320 | click or scan EU-EC-10009514617 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13321 | click or scan EU-EC-10009514570 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Brain oedema (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13322 | click or scan EU-EC-10009514520 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Tonsillar inflammation (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13323 | click or scan EU-EC-10009514494 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Epilepsy (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13324 | click or scan EU-EC-10009513564 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 13325 | click or scan EU-EC-10009513473 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13326 | click or scan EU-EC-10009513394 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13327 | click or scan EU-EC-10009513211 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13328 | click or scan EU-EC-10009513138 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13329 | click or scan EU-EC-10009513089 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13330 | click or scan EU-EC-10009512942 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (3d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**), Chills (3d - Fatal - **Results in Death**), Fall (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13331 | click or scan EU-EC-10009512605 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Gastric haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13332 | click or scan EU-EC-10009512602 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Aneurysm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13333 | click or scan EU-EC-10009512312 | | 2021-07-28 | Healthcare Professional | Non EEA | Not Specified | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13334 | click or scan EU-EC-10009512271 | | 2021-07-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia paroxysmal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13335 | click or scan EU-EC-10009512257 | | 2021-07-28 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hydrops foetalis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 13336 | click or scan EU-EC-10009511943 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cushing's syndrome (n/a - Fatal - **Results in Death**), Pemphigoid (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13337 | click or scan EU-EC-10009511453 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13338 | click or scan EU-EC-10009511339 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13339 | click or scan EU-EC-10009511332 | | 2021-07-28 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Foetal cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13340 | click or scan EU-EC-10009511167 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | ADAMTS13 activity decreased (n/a - Fatal - **Results in Death**), Autoimmune disorder (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | BIKTARVY [EMTRICITABINE, TENOFOVIR ALAFENAMIDE, BICTEGRAVIR] (S - n/a - Unknown - [n/a - 1 {DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [FLUCONAZOLE] (S - n/a - Unknown - [n/a - 1 {DF} - n/a]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (S - n/a - Unknown - [n/a - .5 {DF} - n/a]) |
| 13341 | click or scan EU-EC-10009510417 | | 2021-07-28 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Macrocephaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly), PTEN gene mutation (n/a - Fatal - **Results in Death**, Congenital Anomaly), Stillbirth (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 13342 | click or scan EU-EC-10009510397 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Neutropenic sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pancytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13343 | click or scan EU-EC-10009509827 |  | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13344 | click or scan EU-EC-10009507643 |  | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Illness (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13345 | click or scan EU-EC-10009506634 |  | 2021-07-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13346 | click or scan EU-EC-10009506591 |  | 2021-07-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13347 | click or scan EU-EC-10009506111 |  | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral artery thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Prosthetic cardiac valve thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Skin haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13348 | click or scan EU-EC-10009504725 |  | 2021-07-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13349 | click or scan EU-EC-10009504443 |  | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13350 | click or scan EU-EC-10009504399 |  | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Encephalitis (n/a - Fatal - **Results in Death**), Listeriosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13351 | click or scan EU-EC-10009504178 |  | 2021-07-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Unknown - ), Cardiac disorder (n/a - Unknown - ), Chest discomfort (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Illness (n/a - Unknown - ), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Insomnia (n/a - Unknown - ), Lung disorder (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 13352 | click or scan EU-EC-10009503859 |  | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13353 | click or scan EU-EC-10009503746 | | 2021-07-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13354 | click or scan EU-EC-10009503722 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Left ventricular failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13355 | click or scan EU-EC-10009503654 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13356 | click or scan EU-EC-10009501142 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ascites (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13357 | click or scan EU-EC-10009502147 | | 2021-07-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (1d - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 13358 | click or scan EU-EC-10009500701 | | 2021-07-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic shock (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Burning sensation (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paralysis (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13359 | click or scan EU-EC-10009500637 | | 2021-07-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13360 | click or scan EU-EC-10009500588 | | 2021-07-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Aphasia (n/a - Unknown - ), Blood potassium increased (n/a - Unknown - ), Cough (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Melaena (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Swelling (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13361 | click or scan EU-EC-10009499645 | | 2021-07-27 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 13362 | click or scan EU-EC-10009498491 | | 2021-07-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13363 | click or scan EU-EC-10009498291 | | 2021-07-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oesophageal carcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13364 | click or scan EU-EC-10009498201 | | 2021-07-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (1d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (21d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13365 | click or scan EU-EC-10009497777 | | 2021-07-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Constipation (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13366 | click or scan EU-EC-10009497013 | | 2021-07-27 | Healthcare Professional | EEA | 65-85 Years | Male | Large intestine perforation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13367 | click or scan EU-EC-10009496455 | | 2021-07-27 | Healthcare Professional | EEA | 18-64 Years | Female | Budd-Chiari syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Polycythaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13368 | click or scan EU-EC-10009496284 | | 2021-07-27 | Healthcare Professional | EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pancreatitis chronic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13369 | click or scan EU-EC-10009495731 | | 2021-07-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13370 | click or scan EU-EC-10009495717 | | 2021-07-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13371 | click or scan EU-EC-10009495685 | | 2021-07-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13372 | click or scan EU-EC-10009495311 | | 2021-07-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Microcytic anaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13373** | click or scan EU-EC-10009494015 |  | 2021-07-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **13374** | click or scan EU-EC-10009493519 |  | 2021-07-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13375** | click or scan EU-EC-10009493412 |  | 2021-07-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Immobile (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13376** | click or scan EU-EC-10009492466 |  | 2021-07-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Injection site swelling (n/a - Unknown - ), Irritability (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rash (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| **13377** | click or scan EU-EC-10009491495 |  | 2021-07-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - ), Cellulitis (n/a - Unknown - Other Medically Important Condition), Dementia (n/a - Unknown - Other Medically Important Condition), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13378** | click or scan EU-EC-10009490813 |  | 2021-07-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), LEVOFLOXACIN [LEVOFLOXACIN] (S - Urinary tract infection - Not applicable - [1d - 500mg - Oral]) |
| **13379** | click or scan EU-EC-10009490246 |  | 2021-07-27 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (13d - Fatal - **Results in Death**), Cardio-respiratory arrest (13d - Fatal - **Results in Death**), Headache (13d - Fatal - **Results in Death**), Musculoskeletal pain (13d - Fatal - **Results in Death**), Pyrexia (13d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **13380** | click or scan EU-EC-10009488381 |  | 2021-07-27 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (12d - Fatal - **Results in Death**), Pyrexia (12d - Fatal - **Results in Death**), SARS-CoV-2 test positive (12d - Fatal - **Results in Death**), Vaccination failure (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| **13381** | click or scan EU-EC-10009489328 |  | 2021-07-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - ), Thrombosis (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13382 | click or scan EU-EC-10009489071 | | 2021-07-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13383 | click or scan EU-EC-10009489062 | | 2021-07-26 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Limb injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13384 | click or scan EU-EC-10009488081 | | 2021-07-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Maternal exposure during pregnancy (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13385 | click or scan EU-EC-10009487841 | | 2021-07-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13386 | click or scan EU-EC-10009487498 | | 2021-07-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13387 | click or scan EU-EC-10009487495 | | 2021-07-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13388 | click or scan EU-EC-10009487238 | | 2021-07-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gait inability (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoglycaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13389 | click or scan EU-EC-10009485875 | | 2021-07-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Exsanguination (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13390 | click or scan EU-EC-10009485862 | | 2021-07-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13391 | click or scan EU-EC-10009485537 | | 2021-07-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13392 | click or scan EU-EC-10009484332 | | 2021-07-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Carotid artery thrombosis (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 13393 | click or scan EU-EC-10009484321 | | 2021-07-26 | Healthcare Professional | EEA | 65-85 Years | Male | Lung disorder (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 13394 | click or scan EU-EC-10009484263 | | 2021-07-26 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 13395 | click or scan EU-EC-10009484232 | | 2021-07-26 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (1h - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 13396 | click or scan EU-EC-10009484196 | | 2021-07-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 13397 | click or scan EU-EC-10009483277 | | 2021-07-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiomyopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Haemophilus infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 13398 | click or scan EU-EC-10009482538 | | 2021-07-26 | Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13399 | click or scan EU-EC-10009482362 | | 2021-07-26 | Healthcare Professional | EEA | Not Specified | Female | Aphasia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 13400 | click or scan EU-EC-10009482207 | | 2021-07-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13401 | click or scan EU-EC-10009481621 | | 2021-07-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - .3mL - Intramuscular]) |
| 13402 | click or scan EU-EC-10009481328 | | 2021-07-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Illness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13403 | click or scan EU-EC-10009481232 | | 2021-07-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arthralgia (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - ), Spinal osteoarthritis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13404 | click or scan EU-EC-10009481212 | | 2021-07-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13405 | click or scan EU-EC-10009480839 | | 2021-07-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13406 | click or scan EU-EC-10009480672 | | 2021-07-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13407 | click or scan EU-EC-10009480191 | | 2021-07-26 | Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - ), Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13408 | click or scan EU-EC-10009478822 | | 2021-07-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13409 | click or scan EU-EC-10009478496 | | 2021-07-26 | Healthcare Professional | Non EEA | Not Specified | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13410** | click or scan EU-EC-10009478452 |  | 2021-07-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Haematochezia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Hepatic function abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammatory marker increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mesenteric arterial occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory acidosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13411** | click or scan EU-EC-10009478297 |  | 2021-07-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Interchange of vaccine products (n/a - Fatal - **Results in Death**), Off label use (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **13412** | click or scan EU-EC-10009478222 |  | 2021-07-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tenderness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13413** | click or scan EU-EC-10009478187 |  | 2021-07-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13414** | click or scan EU-EC-10009478186 |  | 2021-07-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13415** | click or scan EU-EC-10009476420 |  | 2021-07-25 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Coronary artery stenosis (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), METHOTREXATE [METHOTREXATE] (S - Rheumatoid arthritis - Not applicable - [n/a - n/a - n/a]) |
| **13416** | click or scan EU-EC-10009475186 |  | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **13417** | click or scan EU-EC-10009475181 |  | 2021-07-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Chest pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Contusion (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Deja vu (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Jugular vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Neck pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Platelet anisocytosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13418 | click or scan EU-EC-10009475178 | | 2021-07-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Foetal exposure during pregnancy (n/a - Unknown - **Results in Death**), Foetal heart rate abnormal (n/a - Unknown - **Results in Death**), Low birth weight baby (n/a - Unknown - **Results in Death**), Stillbirth (1d - Fatal - **Results in Death**), Umbilical cord around neck (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 13419 | click or scan EU-EC-10009475170 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypopnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine output decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13420 | click or scan EU-EC-10009475167 | | 2021-07-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Arteriosclerosis coronary artery (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Not Recovered/Not Resolved - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13421 | click or scan EU-EC-10009475133 | | 2021-07-24 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congestive cardiomyopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13422 | click or scan EU-EC-10009474963 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13423 | click or scan EU-EC-10009474935 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**), Cough (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13424 | click or scan EU-EC-10009474931 | | 2021-07-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular dysfunction (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial strain imaging (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 13425 | click or scan EU-EC-10009474925 | | 2021-07-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13426 | click or scan EU-EC-10009474924 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**), Diarrhoea (2d - Recovered/Resolved - **Results in Death**), Facial paralysis (n/a - Not Recovered/Not Resolved - **Results in Death**), Pupil fixed (n/a - Not Recovered/Not Resolved - **Results in Death**), Pyrexia (2d - Recovered/Resolved - **Results in Death**), Rash erythematous (2d - Recovered/Resolved - **Results in Death**), Vomiting (1d - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13427 | click or scan EU-EC-10009474807 | | 2021-07-24 | Non Healthcare Professional | Non EEA | Not Specified | Male | Influenza like illness (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13428 | click or scan EU-EC-10009474667 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Unknown - **Results in Death**), Confusional state (n/a - Recovered/Resolved - **Results in Death**), Dyspnoea (n/a - Recovered/Resolved - **Results in Death**), Lethargy (n/a - Recovered/Resolved - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13429 | click or scan EU-EC-10009474399 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13430 | click or scan EU-EC-10009474382 | | 2021-07-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13431 | click or scan EU-EC-10009474381 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (5d - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13432 | click or scan EU-EC-10009474374 | | 2021-07-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Somnolence (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Visual impairment (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vitreous floaters (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13433 | click or scan EU-EC-10009474150 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13434 | click or scan EU-EC-10009474117 | | 2021-07-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Jaundice (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Metastasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13435 | click or scan EU-EC-10009474074 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (58d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13436 | click or scan EU-EC-10009474068 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**), Abdominal pain upper (n/a - Unknown - **Results in Death**), Back pain (n/a - Unknown - **Results in Death**), Circulatory collapse (1d - Fatal - **Results in Death**), Pain (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13437 | click or scan EU-EC-10009474058 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13438 | click or scan EU-EC-10009474056 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13439 | click or scan EU-EC-10009473958 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13440 | click or scan EU-EC-10009473913 | | 2021-07-24 | Non Healthcare Professional | Non EEA | Not Specified | Male | Confusional state (n/a - Unknown - **Results in Death**), Dyspepsia (n/a - Unknown - **Results in Death**), Joint lock (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**), Pharyngeal swelling (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13441 | click or scan EU-EC-10009473576 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13442 | click or scan EU-EC-10009473476 | | 2021-07-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Brain stem infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13443 | click or scan EU-EC-10009473475 | | 2021-07-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (1d - Not Recovered/Not Resolved - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13444 | click or scan EU-EC-10009471457 | | 2021-07-24 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (10d - Fatal - **Results in Death**), Pneumonitis (10d - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**), Renal failure (10d - Fatal - **Results in Death**), Septic shock (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13445 | click or scan EU-EC-10009471456 | | 2021-07-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**), Vaccination failure (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13446 | click or scan EU-EC-10009471452 | | 2021-07-24 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 13447 | click or scan EU-EC-10009471446 | | 2021-07-24 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 13448 | click or scan EU-EC-10009472325 | | 2021-07-23 | Healthcare Professional | EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13449 | click or scan EU-EC-10009471881 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypertensive heart disease (n/a - Fatal - **Results in Death**), Ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13450 | click or scan EU-EC-10009471867 | | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13451 | click or scan EU-EC-10009471835 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13452 | click or scan EU-EC-10009471632 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autoimmune hepatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13453 | click or scan EU-EC-10009471079 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - **Results in Death**), Intestinal infarction (n/a - Fatal - **Results in Death**), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Photophobia (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Unknown - Other Medically Important Condition), Rectal haemorrhage (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Visceral venous thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 13454 | click or scan EU-EC-10009470379 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13455 | click or scan EU-EC-10009470167 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13456 | click or scan EU-EC-10009470159 | | 2021-07-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13457 | click or scan EU-EC-10009470056 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13458 | click or scan EU-EC-10009470021 | | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13459 | click or scan EU-EC-10009469992 | | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Body temperature decreased (n/a - Unknown - Other Medically Important Condition), Embolic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13460 | click or scan EU-EC-10009469885 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cholecystitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Cholelithiasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13461 | click or scan EU-EC-10009469825 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13462 | click or scan EU-EC-10009469623 | | 2021-07-23 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Pancreas infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13463 | click or scan EU-EC-10009469512 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**), Seasonal allergy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13464** | click or scan EU-EC-10009469398 |  | 2021-07-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mucosal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Partial seizures (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **13465** | click or scan EU-EC-10009468761 |  | 2021-07-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Immune system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13466** | click or scan EU-EC-10009468754 |  | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13467** | click or scan EU-EC-10009468574 |  | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [INFLUENZA VACCINE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **13468** | click or scan EU-EC-10009468441 |  | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **13469** | click or scan EU-EC-10009467516 |  | 2021-07-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **13470** | click or scan EU-EC-10009467396 |  | 2021-07-23 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **13471** | click or scan EU-EC-10009467138 |  | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13472** | click or scan EU-EC-10009467063 |  | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Near drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13473 | click or scan EU-EC-10009467036 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 13474 | click or scan EU-EC-10009466212 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13475 | click or scan EU-EC-10009465982 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13476 | click or scan EU-EC-10009465944 | | 2021-07-23 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13477 | click or scan EU-EC-10009465936 | | 2021-07-23 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13478 | click or scan EU-EC-10009465550 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13479 | click or scan EU-EC-10009465542 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Congestive cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hepatic steatosis (n/a - Unknown - ), Hypertrophy (n/a - Unknown - ), Idiopathic pulmonary fibrosis (n/a - Unknown - Other Medically Important Condition), Lung consolidation (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pulmonary thrombosis (n/a - Unknown - Other Medically Important Condition), Stenosis (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13480 | click or scan EU-EC-10009465362 | | 2021-07-23 | Healthcare Professional | EEA | 65-85 Years | Female | Atrial thrombosis (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 13481 | click or scan EU-EC-10009465262 | | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13482 | click or scan EU-EC-10009464857 | | 2021-07-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13483 | click or scan EU-EC-10009464404 | | 2021-07-23 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Rhinorrhoea (3d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13484 | click or scan EU-EC-10009463939 | | 2021-07-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13485 | click or scan EU-EC-10009463880 | | 2021-07-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13486 | click or scan EU-EC-10009463387 | | 2021-07-23 | Healthcare Professional | EEA | 18-64 Years | Male | Embolism (n/a - Fatal - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 13487 | click or scan EU-EC-10009463359 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13488 | click or scan EU-EC-10009463048 | | 2021-07-23 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - ), Antiphospholipid antibodies positive (n/a - Fatal - **Results in Death**), Aortic thrombosis (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Diarrhoea (3d - Unknown - ), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Heparin-induced thrombocytopenia test positive (n/a - Unknown - Other Medically Important Condition), Hepatic vein thrombosis (n/a - Fatal - **Results in Death**), Impaired work ability (n/a - Unknown - ), Intestinal infarction (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Unknown - ), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**), Neck pain (n/a - Unknown - Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Splenic infarction (n/a - Fatal - **Results in Death**), Splenic vein thrombosis (n/a - Fatal - **Results in Death**), Spontaneous heparin-induced thrombocytopenia syndrome (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13489 | click or scan EU-EC-10009462862 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bacteraemia (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13490 | click or scan EU-EC-10009462250 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Enterobacter sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13491** | click or scan EU-EC-10009462149 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **13492** | click or scan EU-EC-10009462018 | | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13493** | click or scan EU-EC-10009461768 | | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **13494** | click or scan EU-EC-10009461747 | | 2021-07-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (13d - Fatal - **Results in Death**, Life Threatening), Malaise (13d - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (13d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **13495** | click or scan EU-EC-10009461563 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **13496** | click or scan EU-EC-10009461415 | | 2021-07-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fibrin D dimer increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic infarction (n/a - Unknown - Other Medically Important Condition), Intestinal infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Splenic infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13497** | click or scan EU-EC-10009461019 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13498** | click or scan EU-EC-10009460868 | | 2021-07-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Unknown - ), Bedridden (n/a - Unknown - ), Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depersonalisation/derealisation disorder (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Food aversion (n/a - Unknown - ), Malaise (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Neoplasm malignant (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pallor (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Weight bearing difficulty (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **13499** | click or scan EU-EC-10009460597 | | 2021-07-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **13500** | click or scan EU-EC-10009460103 | | 2021-07-23 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13501 | click or scan EU-EC-10009459967 | | 2021-07-23 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13502 | click or scan EU-EC-10009459696 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13503 | click or scan EU-EC-10009459574 | | 2021-07-22 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intravenous (not otherwise specified)]) |
| 13504 | click or scan EU-EC-10009459455 | | 2021-07-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Arthritis (n/a - Unknown - ), Headache (n/a - Recovered/Resolved - ), Injection site pain (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13505 | click or scan EU-EC-10009458917 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (7d - Fatal - **Results in Death**), Cerebral infarction (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 13506 | click or scan EU-EC-10009458709 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13507 | click or scan EU-EC-10009458670 | | 2021-07-22 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Basilar artery occlusion (1d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (11min - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13508 | click or scan EU-EC-10009458345 | | 2021-07-22 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 13509 | click or scan EU-EC-10009458290 | | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13510 | click or scan EU-EC-10009457202 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13511 | click or scan EU-EC-10009457163 |  | 2021-07-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13512 | click or scan EU-EC-10009456924 |  | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13513 | click or scan EU-EC-10009456872 |  | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Presyncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13514 | click or scan EU-EC-10009456825 |  | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mediastinal mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13515 | click or scan EU-EC-10009456766 |  | 2021-07-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Blindness (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13516 | click or scan EU-EC-10009456369 |  | 2021-07-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13517 | click or scan EU-EC-10009456260 |  | 2021-07-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13518 | click or scan EU-EC-10009456061 |  | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13519 | click or scan EU-EC-10009456056 |  | 2021-07-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cellulitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13520 | click or scan EU-EC-10009455795 | | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13521 | click or scan EU-EC-10009455676 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - ), Pancreatitis necrotising (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13522 | click or scan EU-EC-10009455489 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Craniocerebral injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General symptom (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13523 | click or scan EU-EC-10009455420 | | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic eosinophilic leukaemia (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eosinophilia (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Large intestinal ulcer (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oesophageal ulcer (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13524 | click or scan EU-EC-10009454950 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardioversion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory tract congestion (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13525 | click or scan EU-EC-10009454853 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13526 | click or scan EU-EC-10009454731 | | 2021-07-22 | Healthcare Professional | EEA | 18-64 Years | Male | Polyneuropathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 13527 | click or scan EU-EC-10009454728 | | 2021-07-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13528 | click or scan EU-EC-10009454727 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (6d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |
| 13529 | click or scan EU-EC-10009454679 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 13530 | click or scan EU-EC-10009454644 | | 2021-07-22 | Healthcare Professional | EEA | Not Specified | Not Specified | Pulmonary malformation (1d - Fatal - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Transplacental]) |
| 13531 | click or scan EU-EC-10009454602 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13532 | click or scan EU-EC-10009454525 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (1d - Unknown - Caused/Prolonged Hospitalisation), Cervical vertebral fracture (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13533 | click or scan EU-EC-10009454524 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Partial seizures (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13534 | click or scan EU-EC-10009453912 | | 2021-07-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13535 | click or scan EU-EC-10009453559 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acquired haemophilia (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gallbladder rupture (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemobilia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13536 | click or scan EU-EC-10009453460 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13537 | click or scan EU-EC-10009453453 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13538 | click or scan EU-EC-10009453442 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (47d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cognitive disorder (47d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (47d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (47d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (47d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematuria (47d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Skin exfoliation (47d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13539 | click or scan EU-EC-10009453001 | | 2021-07-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13540 | click or scan EU-EC-10009452799 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13541 | click or scan EU-EC-10009452704 | | 2021-07-22 | Healthcare Professional | Non EEA | Not Specified | Female | Cell death (n/a - Unknown - ), Extramedullary haemopoiesis (n/a - Unknown - ), Extremity contracture (n/a - Unknown - ), Joint range of motion decreased (n/a - Unknown - ), Maternal exposure timing unspecified (n/a - Fatal - **Results in Death**), Musculoskeletal disorder (n/a - Unknown - ), Placental disorder (n/a - Fatal - **Results in Death**), Premature baby (n/a - Unknown - Other Medically Important Condition), Scoliosis (n/a - Unknown - ), Visceral oedema (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 13542 | click or scan EU-EC-10009452492 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13543 | click or scan EU-EC-10009452477 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13544 | click or scan EU-EC-10009452298 | | 2021-07-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13545 | click or scan EU-EC-10009452222 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolic stroke (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic hepatitis (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Refusal of treatment by relative (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure anoxic (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Swelling (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13546 | click or scan EU-EC-10009452218 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13547 | click or scan EU-EC-10009452138 | | 2021-07-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Fatigue (n/a - Fatal - **Results in Death**), Fear of falling (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**), Limb injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13548 | click or scan EU-EC-10009450897 | | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis (1d - Fatal - **Results in Death**), Arteriosclerosis coronary artery (1d - Fatal - **Results in Death**), Cardiac tamponade (1d - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (1d - Fatal - **Results in Death**), Coronary artery occlusion (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13549 | click or scan EU-EC-10009450707 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13550 | click or scan EU-EC-10009450563 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13551 | click or scan EU-EC-10009450490 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Delirium (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Parainfluenzae virus infection (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13552 | click or scan EU-EC-10009450214 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13553 | click or scan EU-EC-10009449856 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Intracardiac thrombus (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13554 | click or scan EU-EC-10009449829 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain neoplasm (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13555 | click or scan EU-EC-10009449720 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13556 | click or scan EU-EC-10009449605 | | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (18d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13557 | click or scan EU-EC-10009449518 | | 2021-07-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse reaction (n/a - Unknown - ), Back pain (n/a - Unknown - ), Bedridden (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Eye movement disorder (n/a - Unknown - ), Hypokinesia (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ), Malaise (n/a - Unknown - ), Neck pain (n/a - Unknown - ), Sensory loss (n/a - Unknown - ), Swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13558 | click or scan EU-EC-10009449463 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13559 | click or scan EU-EC-10009449461 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13560 | click or scan EU-EC-10009449460 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13561 | click or scan EU-EC-10009449440 | | 2021-07-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13562 | click or scan EU-EC-10009449365 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Fluid intake reduced (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13563 | click or scan EU-EC-10009449341 | | 2021-07-22 | Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection rupture (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 13564 | click or scan EU-EC-10009449095 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13565 | click or scan EU-EC-10009449088 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13566 | click or scan EU-EC-10009449017 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haematoma (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13567 | click or scan EU-EC-10009448914 | | 2021-07-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Brain stem infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 13568 | click or scan EU-EC-10009448724 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blindness unilateral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cutaneous vasculitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyschromatopsia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Photopsia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vasculitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vision blurred (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Visual impairment (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vitreous floaters (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Weight bearing difficulty (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13569 | click or scan EU-EC-10009448697 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13570 | click or scan EU-EC-10009448549 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Herpes zoster (65d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13571 | click or scan EU-EC-10009448519 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13572 | click or scan EU-EC-10009448508 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (111d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13573 | click or scan EU-EC-10009448350 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Amnesia (58d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (58d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (58d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (58d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Incoherent (58d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (58d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (58d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13574 | click or scan EU-EC-10009448324 | | 2021-07-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13575 | click or scan EU-EC-10009447527 | | 2021-07-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13576 | click or scan EU-EC-10009446934 | | 2021-07-22 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13577 | click or scan EU-EC-10009446883 | | 2021-07-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13578 | click or scan EU-EC-10009446871 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Female | Septic shock (15d - Fatal - **Results in Death**), Thrombosis (15d - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 13579 | click or scan EU-EC-10009446751 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Male | Diverticular perforation (n/a - Fatal - **Results in Death**), Enterovesical fistula (n/a - Fatal - **Results in Death**), Shock haemorrhagic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13580 | click or scan EU-EC-10009446745 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Rhabdomyolysis (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13581 | click or scan EU-EC-10009446698 | | 2021-07-22 | Healthcare Professional | EEA | 65-85 Years | Male | Acute coronary syndrome (0d - Fatal - **Results in Death**), Anaemia (0d - Fatal - **Results in Death**), Chest pain (0d - Fatal - **Results in Death**), Haematuria (0d - Fatal - **Results in Death**), Thrombocytopenia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - Intramuscular]) |
| 13582 | click or scan EU-EC-10009446323 | | 2021-07-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13583 | click or scan EU-EC-10009446255 | | 2021-07-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13584 | click or scan EU-EC-10009446225 | | 2021-07-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (1d - Fatal - **Results in Death**), Skin discolouration (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13585 | click or scan EU-EC-10009446199 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspepsia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling hot (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13586 | click or scan EU-EC-10009446000 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (21d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (21d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13587 | click or scan EU-EC-10009445971 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13588 | click or scan EU-EC-10009445949 | | 2021-07-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (15d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (15d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ), Dyspnoea (15d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (22d - Recovered/Resolved - ), Lung infiltration (15d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13589 | click or scan EU-EC-10009445878 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13590 | click or scan EU-EC-10009445613 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13591 | click or scan EU-EC-10009445590 | | 2021-07-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ventricle rupture (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13592 | click or scan EU-EC-10009445526 | | 2021-07-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Completed suicide (1d - Fatal - **Results in Death**, Other Medically Important Condition), Suicidal ideation (18d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13593 | click or scan EU-EC-10009445440 | | 2021-07-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13594 | click or scan EU-EC-10009445328 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Female | Portosplenomesenteric venous thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13595 | click or scan EU-EC-10009445158 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Female | Capillary leak syndrome (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13596 | click or scan EU-EC-10009445135 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13597 | click or scan EU-EC-10009445070 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hyponatraemia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13598 | click or scan EU-EC-10009444803 | | 2021-07-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (4d - Fatal - **Results in Death**), Chills (4d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), Haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13599 | click or scan EU-EC-10009444328 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13600 | click or scan EU-EC-10009444291 | | 2021-07-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hepatomegaly (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13601 | click or scan EU-EC-10009444112 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13602 | click or scan EU-EC-10009443843 | | 2021-07-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Foetal cardiac arrest (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Unknown - ), Stillbirth (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 13603 | click or scan EU-EC-10009443383 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13604 | click or scan EU-EC-10009443239 | | 2021-07-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 13605 | click or scan EU-EC-10009443238 | | 2021-07-21 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13606 | click or scan EU-EC-10009442688 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13607 | click or scan EU-EC-10009442021 | | 2021-07-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Faeces discoloured (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Taste disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13608 | click or scan EU-EC-10009441904 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13609 | click or scan EU-EC-10009441220 | | 2021-07-21 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13610 | click or scan EU-EC-10009441219 | | 2021-07-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13611 | click or scan EU-EC-10009441189 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 13612 | click or scan EU-EC-10009441083 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 13613 | click or scan EU-EC-10009441080 | | 2021-07-21 | Healthcare Professional | EEA | More than 85 Years | Male | Haemorrhagic stroke (9d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a]) |
| 13614 | click or scan EU-EC-10009441077 | | 2021-07-21 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13615 | click or scan EU-EC-10009440094 | | 2021-07-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Organ failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13616 | click or scan EU-EC-10009439919 | | 2021-07-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13617 | click or scan EU-EC-10009439204 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Femoral artery embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ophthalmic vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Periorbital infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Splenic vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13618 | click or scan EU-EC-10009439125 | | 2021-07-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13619 | click or scan EU-EC-10009438415 | | 2021-07-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13620 | click or scan EU-EC-10009438115 | | 2021-07-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Nephritis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13621 | click or scan EU-EC-10009437417 | | 2021-07-21 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13622 | click or scan EU-EC-10009437319 | | 2021-07-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13623 | click or scan EU-EC-10009436769 | | 2021-07-21 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening), Chest pain (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13624 | click or scan EU-EC-10009436754 | | 2021-07-21 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain lower (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [85d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13625 | click or scan EU-EC-10009436031 | | 2021-07-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13626 | click or scan EU-EC-10009434264 | | 2021-07-21 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (0d - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 13627 | click or scan EU-EC-10009434262 | | 2021-07-21 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX (S - n/a - n/a - [n/a - .5mL - n/a]) |
| 13628 | click or scan EU-EC-10009434188 | | 2021-07-21 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (81d - Fatal - **Results in Death**), Autoimmune pancreatitis (81d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13629 | click or scan EU-EC-10009434168 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (0d - Fatal - **Results in Death**), Asthenia (0d - Fatal - **Results in Death**), Hyperpyrexia (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 13630 | click or scan EU-EC-10009433989 | | 2021-07-21 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 13631 | click or scan EU-EC-10009432379 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13632 | click or scan EU-EC-10009432234 | | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Gastrointestinal disorder (40d - Fatal - **Results in Death**), Mass (40d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13633 | click or scan EU-EC-10009431898 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**), Sudden death (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - n/a]) |
| 13634 | click or scan EU-EC-10009431872 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13635** | click or scan EU-EC-10009431866 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13636** | click or scan EU-EC-10009431032 | | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **13637** | click or scan EU-EC-10009430683 | | 2021-07-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Amnesia (42d - Fatal - **Results in Death**), Balance disorder (42d - Fatal - **Results in Death**), Fatigue (42d - Fatal - **Results in Death**), Headache (42d - Fatal - **Results in Death**), Hot flush (42d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Cutaneous]) |
| **13638** | click or scan EU-EC-10009430636 | | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (3d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haematuria (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pancytopenia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **13639** | click or scan EU-EC-10009430549 | | 2021-07-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **13640** | click or scan EU-EC-10009430386 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13641** | click or scan EU-EC-10009430278 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pancreatitis acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13642** | click or scan EU-EC-10009430249 | | 2021-07-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13643** | click or scan EU-EC-10009430151 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **13644** | click or scan EU-EC-10009429851 | | 2021-07-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Enuresis (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**), Oral candidiasis (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **13645** | click or scan EU-EC-10009429826 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13646 | click or scan EU-EC-10009429807 | | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13647 | click or scan EU-EC-10009429761 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Haematemesis (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**), Oesophageal haemorrhage (0d - Fatal - **Results in Death**) | CABOMETYX [CABOZANTINIB] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SPIKEVAX (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), [ENALAPRIL MALEATE] (S - Hypertension - n/a - [n/a - n/a - n/a]) |
| 13648 | click or scan EU-EC-10009429755 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13649 | click or scan EU-EC-10009429712 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Arterial haemorrhage (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13650 | click or scan EU-EC-10009429700 | | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Female | Sepsis (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13651 | click or scan EU-EC-10009429631 | | 2021-07-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Dysuria (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Cutaneous]) |
| 13652 | click or scan EU-EC-10009428406 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13653 | click or scan EU-EC-10009427621 | | 2021-07-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13654 | click or scan EU-EC-10009427164 | | 2021-07-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bacterial infection (n/a - Recovered/Resolved - ), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovering/Resolving - ), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13655 | click or scan EU-EC-10009426467 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (7d - Fatal - **Results in Death**), Pneumonitis (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13656 | click or scan EU-EC-10009425733 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13657 | click or scan EU-EC-10009425304 |  | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13658 | click or scan EU-EC-10009425250 |  | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13659 | click or scan EU-EC-10009425204 |  | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - n/a]) |
| 13660 | click or scan EU-EC-10009423836 |  | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (5d - Fatal - **Results in Death**), Cavernous sinus thrombosis (5d - Fatal - **Results in Death**), Headache (5d - Fatal - **Results in Death**), Seizure (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 13661 | click or scan EU-EC-10009423765 |  | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 13662 | click or scan EU-EC-10009423711 |  | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonitis (3d - Fatal - **Results in Death**), Respiratory failure (3d - Fatal - **Results in Death**), Sepsis (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13663 | click or scan EU-EC-10009423159 |  | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**), Cardiac tamponade (0d - Fatal - **Results in Death**), Chest pain (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13664 | click or scan EU-EC-10009422999 |  | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13665 | click or scan EU-EC-10009422769 |  | 2021-07-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13666 | click or scan EU-EC-10009422674 |  | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hallucination, auditory (n/a - Unknown - Other Medically Important Condition), Hyperkinesia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**), Soliloquy (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13667 | click or scan EU-EC-10009422662 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Coma scale abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation abnormal (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13668 | click or scan EU-EC-10009422582 | | 2021-07-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13669 | click or scan EU-EC-10009422258 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Hypocapnia (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 13670 | click or scan EU-EC-10009422122 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Terminal state (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 13671 | click or scan EU-EC-10009422107 | | 2021-07-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 - Dose not changed - [n/a - n/a - Cutaneous]) |
| 13672 | click or scan EU-EC-10009422063 | | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13673 | click or scan EU-EC-10009421509 | | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13674 | click or scan EU-EC-10009419065 | | 2021-07-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dependence on respirator (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13675 | click or scan EU-EC-10009418403 | | 2021-07-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13676 | click or scan EU-EC-10009418359 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13677 | click or scan EU-EC-10009418335 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13678 | click or scan EU-EC-10009418309 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13679 | click or scan EU-EC-10009418291 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Anaemia (19d - Fatal - **Results in Death**), Cardiac failure (19d - Fatal - **Results in Death**), Dyspnoea (19d - Fatal - **Results in Death**), Pulmonary mass (19d - Fatal - **Results in Death**), Respiratory acidosis (19d - Fatal - **Results in Death**), Respiratory failure (19d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 13680 | click or scan EU-EC-10009418265 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13681 | click or scan EU-EC-10009417448 | | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13682 | click or scan EU-EC-10009417394 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13683 | click or scan EU-EC-10009416972 | | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Female | Asymptomatic COVID-19 (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13684 | click or scan EU-EC-10009416636 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 13685 | click or scan EU-EC-10009415175 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13686 | click or scan EU-EC-10009414945 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 13687 | click or scan EU-EC-10009414574 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (1d - Fatal - **Results in Death**), Haemolysis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13688 | click or scan EU-EC-10009414564 | | 2021-07-20 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13689 | click or scan EU-EC-10009414261 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13690 | click or scan EU-EC-10009414083 | | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Cardiac valve disease (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13691 | click or scan EU-EC-10009414080 | | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13692 | click or scan EU-EC-10009414001 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13693 | click or scan EU-EC-10009413970 | | 2021-07-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**), Swelling (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13694 | click or scan EU-EC-10009413911 | | 2021-07-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Zoonotic bacterial infection (n/a - Fatal - **Results in Death**, Life Threatening, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13695 | click or scan EU-EC-10009413881 | | 2021-07-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13696 | click or scan EU-EC-10009413276 | | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13697 | click or scan EU-EC-10009413253 | | 2021-07-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (99d - Fatal - **Results in Death**), Confusional state (99d - Fatal - **Results in Death**), Vertigo (99d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 13698 | click or scan EU-EC-10009413209 | | 2021-07-20 | Healthcare Professional | EEA | 18-64 Years | Male | Interstitial lung disease (62d - Fatal - **Results in Death**), Pulmonary embolism (62d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13699 | click or scan EU-EC-10009413195 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Not applicable - [n/a - .5mL - Intramuscular]) |
| 13700 | click or scan EU-EC-10009413187 | | 2021-07-20 | Healthcare Professional | EEA | More than 85 Years | Female | Cognitive disorder (39d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13701 | click or scan EU-EC-10009411053 | | 2021-07-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 13702 | click or scan EU-EC-10009412470 | | 2021-07-19 | Non Healthcare Professional | EEA | Not Specified | Male | Death neonatal (n/a - Fatal - **Results in Death**), Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**), Premature baby (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation, Exposure during pregnancy - n/a - [n/a - n/a - n/a]) |
| 13703 | click or scan EU-EC-10009412114 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (13d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (13d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Enterovesical fistula (13d - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (13d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13704 | click or scan EU-EC-10009411832 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Male | Immune-mediated myocarditis (n/a - Fatal - **Results in Death**), Immune-mediated myositis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]), TECENTRIQ 1,200 MG CONCENTRATE FOR SOLUTION FOR INFUSION [ATEZOLIZUMAB] (S - Transitional cell carcinoma - Drug withdrawn - [582d - 1200mg - Intravenous drip]) |
| 13705 | click or scan EU-EC-10009411805 | | 2021-07-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13706 | click or scan EU-EC-10009411673 | | 2021-07-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13707 | click or scan EU-EC-10009411539 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13708 | click or scan EU-EC-10009411524 | | 2021-07-19 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13709 | click or scan EU-EC-10009411431 |  | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (n/a - Unknown - Other Medically Important Condition), Blindness unilateral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Blood fibrinogen decreased (n/a - Unknown - Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic thrombocytopenic purpura (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13710 | click or scan EU-EC-10009411265 |  | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chronic kidney disease (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13711 | click or scan EU-EC-10009411204 |  | 2021-07-19 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13712 | click or scan EU-EC-10009411198 |  | 2021-07-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 13713 | click or scan EU-EC-10009411071 |  | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cholelithiasis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Liver disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13714 | click or scan EU-EC-10009410752 |  | 2021-07-19 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Brain injury (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13715 | click or scan EU-EC-10009410719 |  | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13716 | click or scan EU-EC-10009410634 |  | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Inflammation (n/a - Fatal - **Results in Death**), Local reaction (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sensitisation (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13717 | click or scan EU-EC-10009410454 |  | 2021-07-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13718 | click or scan EU-EC-10009410437 | | 2021-07-19 | Healthcare Professional | Non EEA | Not Specified | Male | Blood creatinine increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure fluctuation (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Renal disorder (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13719 | click or scan EU-EC-10009410307 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13720 | click or scan EU-EC-10009410297 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13721 | click or scan EU-EC-10009410293 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13722 | click or scan EU-EC-10009410109 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13723 | click or scan EU-EC-10009409830 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13724 | click or scan EU-EC-10009409533 | | 2021-07-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13725 | click or scan EU-EC-10009408908 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13726 | click or scan EU-EC-10009408155 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13727 | click or scan EU-EC-10009408123 | | 2021-07-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13728 | click or scan EU-EC-10009408009 | | 2021-07-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [46d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13729 | click or scan EU-EC-10009408004 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13730 | click or scan EU-EC-10009407998 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 13731 | click or scan EU-EC-10009407875 | | 2021-07-19 | Healthcare Professional | EEA | 65-85 Years | Female | Anaphylactic shock (7d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 13732 | click or scan EU-EC-10009407858 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 13733 | click or scan EU-EC-10009407849 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13734 | click or scan EU-EC-10009407660 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (69d - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13735 | click or scan EU-EC-10009407626 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 13736 | click or scan EU-EC-10009407591 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13737 | click or scan EU-EC-10009407372 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13738 | click or scan EU-EC-10009407360 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13739 | click or scan EU-EC-10009407325 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Unknown - ), Disease complication (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13740 | click or scan EU-EC-10009407304 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain compression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebellar infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13741 | click or scan EU-EC-10009407300 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bacteraemia (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13742 | click or scan EU-EC-10009407284 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Female | Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13743 | click or scan EU-EC-10009407259 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anal incontinence (n/a - Unknown - ), Axillary pain (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13744 | click or scan EU-EC-10009407255 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Fatal - **Results in Death**), Breath sounds abnormal (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13745 | click or scan EU-EC-10009407238 | | 2021-07-19 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Hypersensitivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia oral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Miller Fisher syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13746 | click or scan EU-EC-10009407235 | | 2021-07-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (5d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 13747 | click or scan EU-EC-10009406726 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13748 | click or scan EU-EC-10009406517 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Angina unstable (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13749 | click or scan EU-EC-10009406458 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agonal respiration (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ), Dyspnoea (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13750 | click or scan EU-EC-10009406360 | | 2021-07-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13751 | click or scan EU-EC-10009406328 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13752 | click or scan EU-EC-10009406323 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspartate aminotransferase increased (n/a - Unknown - Other Medically Important Condition), Asthma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactate dehydrogenase increased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13753 | click or scan EU-EC-10009406317 | | 2021-07-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13754 | click or scan EU-EC-10009406297 | | 2021-07-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13755 | click or scan EU-EC-10009406287 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - ), Haemoptysis (n/a - Unknown - ), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia bacterial (n/a - Unknown - Other Medically Important Condition), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13756 | click or scan EU-EC-10009406263 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericardial haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13757 | click or scan EU-EC-10009406249 | | 2021-07-19 | Non Healthcare Professional | EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13758 | click or scan EU-EC-10009406241 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13759** | click or scan EU-EC-10009406228 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **13760** | click or scan EU-EC-10009406184 | | 2021-07-19 | Healthcare Professional | EEA | 65-85 Years | Male | Aspiration (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening), Hypertensive crisis (n/a - Fatal - **Results in Death**, Life Threatening), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **13761** | click or scan EU-EC-10009406127 | | 2021-07-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Erythema (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Fatal - **Results in Death**), Hypersensitivity (n/a - Fatal - **Results in Death**), Pruritus (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **13762** | click or scan EU-EC-10009405863 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoosmolar state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **13763** | click or scan EU-EC-10009405617 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13764** | click or scan EU-EC-10009405578 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13765** | click or scan EU-EC-10009405543 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Subdural haematoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13766** | click or scan EU-EC-10009405218 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), Acute respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13767** | click or scan EU-EC-10009403976 | | 2021-07-19 | Healthcare Professional | EEA | 18-64 Years | Male | Muscular weakness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **13768** | click or scan EU-EC-10009403475 | | 2021-07-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **13769** | click or scan EU-EC-10009403331 | | 2021-07-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13770 | click or scan EU-EC-10009403212 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypopnoea (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 13771 | click or scan EU-EC-10009403188 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**), Pyrexia (3d - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13772 | click or scan EU-EC-10009403183 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Hernia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13773 | click or scan EU-EC-10009403055 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13774 | click or scan EU-EC-10009403049 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13775 | click or scan EU-EC-10009402940 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**), Pulse abnormal (n/a - Unknown - Other Medically Important Condition), Pupil fixed (n/a - Unknown - Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Other Medically Important Condition), Slow response to stimuli (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13776 | click or scan EU-EC-10009402762 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Disabling), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Disabling), Hemiparesis (n/a - Fatal - **Results in Death**, Disabling), Paralysis (n/a - Fatal - **Results in Death**, Disabling), Thrombosis (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13777 | click or scan EU-EC-10009402491 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Intracranial aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13778 | click or scan EU-EC-10009402310 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13779 | click or scan EU-EC-10009402276 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyskinesia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sputum increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13780 | click or scan EU-EC-10009402269 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13781 | click or scan EU-EC-10009402242 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea exertional (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13782 | click or scan EU-EC-10009402236 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening), Ventricular tachycardia (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13783 | click or scan EU-EC-10009402107 | | 2021-07-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (7d - Unknown - ), Asthenia (7d - Unknown - ), Cardiac failure acute (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (7d - Unknown - ), Epistaxis (7d - Unknown - ), Fatigue (7d - Unknown - ), Hypotension (7d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13784 | click or scan EU-EC-10009401785 | | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13785 | click or scan EU-EC-10009401658 | | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 13786 | click or scan EU-EC-10009401464 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13787 | click or scan EU-EC-10009401237 | | 2021-07-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13788 | click or scan EU-EC-10009401142 | | 2021-07-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Cough (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pallor (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sinusitis (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Weight decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13789 | click or scan EU-EC-10009401132 | | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13790 | click or scan EU-EC-10009400753 |  | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aspiration (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Decreased activity (251h - Recovered/Resolved With Sequelae - Other Medically Important Condition), Dehydration (251h - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Dysarthria (251h - Recovered/Resolved - Other Medically Important Condition), Eating disorder (n/a - Unknown - Other Medically Important Condition), Hypokinesia (251h - Recovered/Resolved With Sequelae - Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13791 | click or scan EU-EC-10009400540 |  | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Conjunctival haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Factor V deficiency (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intra-abdominal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Small intestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subdural haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13792 | click or scan EU-EC-10009400430 |  | 2021-07-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13793 | click or scan EU-EC-10009400406 |  | 2021-07-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13794 | click or scan EU-EC-10009400338 |  | 2021-07-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Suicide attempt (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13795 | click or scan EU-EC-10009398403 |  | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (9d - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling, Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling, Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 13796 | click or scan EU-EC-10009398265 |  | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13797 | click or scan EU-EC-10009398040 |  | 2021-07-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic embolus (n/a - Unknown - **Results in Death**), Influenza like illness (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Seizure (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13798 | click or scan EU-EC-10009397918 |  | 2021-07-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13799 | click or scan EU-EC-10009397917 |  | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13800** | click or scan EU-EC-10009397884 | | 2021-07-17 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13801** | click or scan EU-EC-10009397842 | | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypophagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sputum discoloured (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **13802** | click or scan EU-EC-10009397841 | | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13803** | click or scan EU-EC-10009397823 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Bronchial oedema (n/a - Unknown - **Results in Death**), Bullous haemorrhagic dermatosis (n/a - Unknown - **Results in Death**), Contusion (n/a - Unknown - **Results in Death**), Epiglottic oedema (n/a - Unknown - **Results in Death**), Hypersensitivity (n/a - Fatal - **Results in Death**), Laryngeal oedema (n/a - Unknown - **Results in Death**), Oedema peripheral (n/a - Unknown - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**), Petechiae (n/a - Unknown - **Results in Death**), Tremor (1d - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **13804** | click or scan EU-EC-10009397492 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (4d - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Constipation (4d - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Intestinal infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13805** | click or scan EU-EC-10009397486 | | 2021-07-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13806** | click or scan EU-EC-10009397484 | | 2021-07-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (19d - Fatal - **Results in Death**), Diarrhoea (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13807** | click or scan EU-EC-10009397483 | | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mesenteric artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13808 | click or scan EU-EC-10009397480 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13809 | click or scan EU-EC-10009397478 | | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (1d - Fatal - **Results in Death**), Fall (n/a - Unknown - **Results in Death**), Tryptase increased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13810 | click or scan EU-EC-10009397321 | | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13811 | click or scan EU-EC-10009397315 | | 2021-07-17 | Healthcare Professional | Non EEA | Not Specified | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 13812 | click or scan EU-EC-10009397296 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neck pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13813 | click or scan EU-EC-10009397259 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Unknown - **Results in Death**), COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**), COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cerebrovascular accident (17d - Fatal - **Results in Death**), Dysphemia (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Hypoaesthesia (n/a - Unknown - **Results in Death**), Lower respiratory tract infection (n/a - Unknown - **Results in Death**), Muscular weakness (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13814 | click or scan EU-EC-10009397254 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling), Myalgia (n/a - Unknown - **Results in Death**, Disabling), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling), Pneumonia (n/a - Fatal - **Results in Death**, Disabling), Pyrexia (7d - Recovered/Resolved - **Results in Death**, Disabling), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13815 | click or scan EU-EC-10009397253 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (2d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (2d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13816 | click or scan EU-EC-10009397184 | | 2021-07-17 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Sepsis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13817 | click or scan EU-EC-10009396632 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13818 | click or scan EU-EC-10009396430 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Groin pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Parenteral]) |
| 13819 | click or scan EU-EC-10009396425 | | 2021-07-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Peripheral swelling (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 13820 | click or scan EU-EC-10009396247 | | 2021-07-17 | Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13821 | click or scan EU-EC-10009396174 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Unknown - **Results in Death**), Left ventricular failure (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 13822 | click or scan EU-EC-10009396156 | | 2021-07-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 13823 | click or scan EU-EC-10009396121 | | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (12d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 13824 | click or scan EU-EC-10009396117 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Cough (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13825 | click or scan EU-EC-10009396116 | | 2021-07-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13826 | click or scan EU-EC-10009396114 |  | 2021-07-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Bladder dysfunction (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Renal failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13827 | click or scan EU-EC-10009395993 |  | 2021-07-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13828 | click or scan EU-EC-10009394980 |  | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Recovered/Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13829 | click or scan EU-EC-10009394806 |  | 2021-07-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 13830 | click or scan EU-EC-10009394765 |  | 2021-07-17 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (0d - Fatal - **Results in Death**), Bradycardia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13831 | click or scan EU-EC-10009394755 |  | 2021-07-17 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13832 | click or scan EU-EC-10009394667 |  | 2021-07-17 | Healthcare Professional | EEA | 65-85 Years | Female | Back pain (6d - Fatal - **Results in Death**), Confusional state (6d - Fatal - **Results in Death**), Headache (6d - Fatal - **Results in Death**), Monoparesis (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13833 | click or scan EU-EC-10009394305 |  | 2021-07-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (n/a - Unknown - ), Aphasia (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Ischaemic cerebral infarction (10d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Renal failure (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ), Urinary tract infection (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13834 | click or scan EU-EC-10009392770 |  | 2021-07-17 | Healthcare Professional | EEA | 18-64 Years | Female | Respiratory arrest (0d - Fatal - **Results in Death**), Respiratory failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13835 | click or scan EU-EC-10009394269 |  | 2021-07-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Blood disorder (n/a - Unknown - ), Cough (8d - Unknown - ), Fatigue (7d - Unknown - ), Impaired work ability (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved With Sequelae - ), Sinusitis (8d - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ), Vomiting (8d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13836 | click or scan EU-EC-10009394139 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrioventricular block complete (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 13837 | click or scan EU-EC-10009393977 | | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac valve disease (n/a - Not Recovered/Not Resolved - **Results in Death**), Circulatory collapse (n/a - Unknown - **Results in Death**), Myocardial ischaemia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13838 | click or scan EU-EC-10009393927 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13839 | click or scan EU-EC-10009393859 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13840 | click or scan EU-EC-10009393739 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Autoimmune disorder (9d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (9d - Fatal - **Results in Death**), Haemolytic anaemia (9d - Fatal - **Results in Death**, Other Medically Important Condition), Immunosuppression (9d - Fatal - **Results in Death**, Other Medically Important Condition), Rheumatoid arthritis (9d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13841 | click or scan EU-EC-10009393597 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia viral (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13842 | click or scan EU-EC-10009393548 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Atrioventricular block (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysstasia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Haemorrhage urinary tract (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stent placement (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13843 | click or scan EU-EC-10009393541 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (2d - Fatal - **Results in Death**, Other Medically Important Condition), Chronic kidney disease (2d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (2d - Fatal - **Results in Death**), Hypertension (2d - Fatal - **Results in Death**), Oesophageal stenosis (2d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13844 | click or scan EU-EC-10009393533 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13845 | click or scan EU-EC-10009393470 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13846 | click or scan EU-EC-10009393422 | | 2021-07-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]), [DROSPIRENONE, ETHINYLESTRADIOL] (S - Contraception - Dose not changed - [n/a - 1 {DF} - Oral]) |
| 13847 | click or scan EU-EC-10009393262 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (10d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (10d - Fatal - **Results in Death**), Left ventricular failure (10d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13848 | click or scan EU-EC-10009393246 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13849 | click or scan EU-EC-10009392627 | | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pain in extremity (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13850 | click or scan EU-EC-10009392232 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13851 | click or scan EU-EC-10009392116 | | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthma (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13852 | click or scan EU-EC-10009392093 | | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**), Vaccination error (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13853 | click or scan EU-EC-10009392063 | | 2021-07-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Neck pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Spinal cord infection (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13854 | click or scan EU-EC-10009391961 | | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13855 | click or scan EU-EC-10009391947 |  | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Renal impairment (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thoracic cavity drainage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13856 | click or scan EU-EC-10009391853 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13857 | click or scan EU-EC-10009391851 |  | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13858 | click or scan EU-EC-10009391849 |  | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Unknown - Other Medically Important Condition), Coronary artery occlusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular tachycardia (0d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13859 | click or scan EU-EC-10009391848 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13860 | click or scan EU-EC-10009391843 |  | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (19d - Fatal - **Results in Death**), Pyrexia (19d - Fatal - **Results in Death**), Respiratory tract congestion (19d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13861 | click or scan EU-EC-10009391578 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atelectasis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myoclonus (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13862 | click or scan EU-EC-10009391556 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**), Aortic dissection (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Lung neoplasm malignant (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13863** | click or scan EU-EC-10009391382 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Unknown]) |
| **13864** | click or scan EU-EC-10009390922 |  | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**), Vaginal haemorrhage (n/a - Unknown - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **13865** | click or scan EU-EC-10009390754 |  | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1h - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **13866** | click or scan EU-EC-10009390602 |  | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Injection site bruising (n/a - Fatal - **Results in Death**), Injection site erythema (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Injection site pruritus (n/a - Fatal - **Results in Death**), Injection site swelling (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **13867** | click or scan EU-EC-10009390424 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13868** | click or scan EU-EC-10009390180 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **13869** | click or scan EU-EC-10009390129 |  | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **13870** | click or scan EU-EC-10009390103 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13871** | click or scan EU-EC-10009390094 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal disorder (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **13872** | click or scan EU-EC-10009390089 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (24d - Fatal - **Results in Death**), Cardiac arrest (24d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Failure to thrive (24d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13873 | click or scan EU-EC-10009390070 | | 2021-07-16 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Chest discomfort (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Hallucination (n/a - Unknown - Other Medically Important Condition), Myasthenia gravis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13874 | click or scan EU-EC-10009389999 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Varicella zoster virus infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13875 | click or scan EU-EC-10009389997 | | 2021-07-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13876 | click or scan EU-EC-10009389927 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13877 | click or scan EU-EC-10009389733 | | 2021-07-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13878 | click or scan EU-EC-10009389627 | | 2021-07-16 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fungal skin infection (n/a - Unknown - ), Urinary tract infection (n/a - Unknown - ), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13879 | click or scan EU-EC-10009389539 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13880 | click or scan EU-EC-10009389496 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [INFLUENZA VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 13881 | click or scan EU-EC-10009389460 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13882 | click or scan EU-EC-10009389456 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13883** | click or scan EU-EC-10009389278 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13884** | click or scan EU-EC-10009389179 |  | 2021-07-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Bronchial hyperreactivity (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**), Wheezing (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13885** | click or scan EU-EC-10009389134 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13886** | click or scan EU-EC-10009388824 |  | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13887** | click or scan EU-EC-10009388749 |  | 2021-07-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **13888** | click or scan EU-EC-10009388624 |  | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (3d - Not Recovered/Not Resolved - ), Nausea (3d - Not Recovered/Not Resolved - ), Pyrexia (3d - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **13889** | click or scan EU-EC-10009388044 |  | 2021-07-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13890** | click or scan EU-EC-10009388021 |  | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Blood pressure decreased (28h - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Hypopnoea (2300min - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Pulse absent (2300min - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Shock (2300min - Recovered/Resolved - Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13891** | click or scan EU-EC-10009387984 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13892** | click or scan EU-EC-10009387962 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13893 | click or scan EU-EC-10009387172 | | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal neoplasm (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13894 | click or scan EU-EC-10009387066 | | 2021-07-16 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13895 | click or scan EU-EC-10009386530 | | 2021-07-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fall (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Incorrect dose administered (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Needle issue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 13896 | click or scan EU-EC-10009386375 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumoconiosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Right ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13897 | click or scan EU-EC-10009386290 | | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 13898 | click or scan EU-EC-10009386259 | | 2021-07-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Herpes zoster (n/a - Unknown - ), Shock haemorrhagic (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13899 | click or scan EU-EC-10009385857 | | 2021-07-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13900 | click or scan<br>EU-EC-10009385535 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Biopsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac valve vegetation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chemotherapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cholangiocarcinoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abdomen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Critical illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracardiac mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laparoscopic surgery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oliguria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ovarian vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paracentesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Scan with contrast (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13901 | click or scan<br>EU-EC-10009384803 | | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 13902 | click or scan<br>EU-EC-10009384692 | | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13903 | click or scan<br>EU-EC-10009384633 | | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13904 | click or scan<br>EU-EC-10009384258 | | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13905 | click or scan EU-EC-10009384215 |  | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13906 | click or scan EU-EC-10009384167 |  | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13907 | click or scan EU-EC-10009383899 |  | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aphasia (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Foot deformity (n/a - Unknown - Other Medically Important Condition), Gaze palsy (n/a - Unknown - Other Medically Important Condition), Hypokinesia (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Productive cough (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13908 | click or scan EU-EC-10009383889 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13909 | click or scan EU-EC-10009383858 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13910 | click or scan EU-EC-10009383422 |  | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Female | Encephalitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 13911 | click or scan EU-EC-10009383417 |  | 2021-07-16 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 13912 | click or scan EU-EC-10009383409 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 13913 | click or scan EU-EC-10009383297 |  | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13914 | click or scan EU-EC-10009383295 | | 2021-07-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13915 | click or scan EU-EC-10009383031 | | 2021-07-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Biliary colic (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hallucination (85d - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic pain (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperventilation (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown - ), Pleural effusion (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep disorder (85d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13916 | click or scan EU-EC-10009382909 | | 2021-07-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13917 | click or scan EU-EC-10009382571 | | 2021-07-16 | Healthcare Professional | EEA | 18-64 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**), Brain stem infarction (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Subclavian artery thrombosis (n/a - Fatal - **Results in Death**), Thrombectomy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 13918 | click or scan EU-EC-10009382427 | | 2021-07-16 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (3d - Fatal - **Results in Death**, Other Medically Important Condition), Coma (3d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Facial paralysis (3d - Fatal - **Results in Death**, Other Medically Important Condition), Ischaemic stroke (3d - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 13919 | click or scan EU-EC-10009382365 | | 2021-07-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - ), Back disorder (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Feeling abnormal (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13920 | click or scan EU-EC-10009382337 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13921 | click or scan EU-EC-10009382167 | | 2021-07-16 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13922 | click or scan EU-EC-10009382163 | | 2021-07-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13923 | click or scan EU-EC-10009382156 | | 2021-07-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Bradycardia (n/a - Unknown - Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13924 | click or scan EU-EC-10009381391 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (80d - Fatal - **Results in Death**), Generalised tonic-clonic seizure (80d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (80d - Fatal - **Results in Death**), Mental status changes (80d - Fatal - **Results in Death**), Muscular weakness (80d - Fatal - **Results in Death**), Speech disorder (80d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13925 | click or scan EU-EC-10009381385 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13926 | click or scan EU-EC-10009381366 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13927 | click or scan EU-EC-10009381366 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13928 | click or scan EU-EC-10009381355 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13929 | click or scan EU-EC-10009381298 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory symptom (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13930 | click or scan EU-EC-10009381273 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Foaming at mouth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Snoring (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13931 | click or scan EU-EC-10009381244 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (56d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (56d - Fatal - **Results in Death**), Influenza like illness (56d - Fatal - **Results in Death**), Lung disorder (56d - Fatal - **Results in Death**), Paraesthesia (56d - Fatal - **Results in Death**), Renal failure (56d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13932 | click or scan EU-EC-10009381139 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diabetes mellitus (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13933 | click or scan EU-EC-10009380992 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aneurysm ruptured (3d - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (3d - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral artery aneurysm (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 13934 | click or scan EU-EC-10009380891 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (81d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13935 | click or scan EU-EC-10009380846 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13936 | click or scan EU-EC-10009380705 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13937 | click or scan EU-EC-10009380670 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13938 | click or scan EU-EC-10009380608 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13939 | click or scan EU-EC-10009380498 | | 2021-07-15 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 13940 | click or scan EU-EC-10009380456 | | 2021-07-15 | Healthcare Professional | EEA | 65-85 Years | Female | Quadriparesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombotic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13941 | click or scan EU-EC-10009380437 | | 2021-07-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Toxicity to various agents (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13942 | click or scan EU-EC-10009380043 | | 2021-07-15 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular - More in ICSR]) |
| 13943 | click or scan EU-EC-10009379962 | | 2021-07-15 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 13944 | click or scan EU-EC-10009379590 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13945 | click or scan EU-EC-10009379376 | | 2021-07-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13946 | click or scan EU-EC-10009379178 | | 2021-07-15 | Healthcare Professional | Non EEA | Not Specified | Female | Condition aggravated (1d - Fatal - **Results in Death**), End stage renal disease (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13947 | click or scan EU-EC-10009379043 | | 2021-07-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13948 | click or scan EU-EC-10009378613 | | 2021-07-15 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (7d - Fatal - **Results in Death**), General physical health deterioration (7d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 13949 | click or scan EU-EC-10009377971 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Ageusia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blood urea increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), CSF protein increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Chills (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Decreased appetite (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dehydration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypernatraemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypogeusia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Paresis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Urinary incontinence (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), White blood cell count increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13950 | click or scan EU-EC-10009377957 | | 2021-07-15 | Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13951 | click or scan EU-EC-10009377939 | | 2021-07-15 | Non Healthcare Professional | EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13952 | click or scan EU-EC-10009377715 | | 2021-07-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Myocardial infarction (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1s - 1 {DF} - Intramuscular]) |
| 13953 | click or scan EU-EC-10009377714 | | 2021-07-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arterial haemorrhage (0d - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Emphysema (1d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (5d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemothorax (1d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung transplant rejection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumothorax (1d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 13954 | click or scan EU-EC-10009377174 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13955 | click or scan EU-EC-10009377125 | | 2021-07-15 | Healthcare Professional | EEA | 65-85 Years | Male | Inflammation (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 13956 | click or scan EU-EC-10009376383 | | 2021-07-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [24d - 2 {DF} - Intramuscular]) |
| 13957 | click or scan EU-EC-10009376379 | | 2021-07-15 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebellar haemorrhage (n/a - Fatal - **Results in Death**), Hydrocephalus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 13958 | click or scan EU-EC-10009376312 | | 2021-07-15 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 13959 | click or scan EU-EC-10009376310 | | 2021-07-15 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13960** | click or scan EU-EC-10009376308 | | 2021-07-15 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| **13961** | click or scan EU-EC-10009376267 | | 2021-07-15 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (28d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **13962** | click or scan EU-EC-10009376038 | | 2021-07-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Back pain (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [5min - 1 {DF} - Intramuscular]) |
| **13963** | click or scan EU-EC-10009375597 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13964** | click or scan EU-EC-10009375588 | | 2021-07-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cytokine storm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13965** | click or scan EU-EC-10009375291 | | 2021-07-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Unknown - **Results in Death**), Dysphagia (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Gait inability (n/a - Unknown - **Results in Death**), Peripheral swelling (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **13966** | click or scan EU-EC-10009374686 | | 2021-07-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13967** | click or scan EU-EC-10009374657 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13968** | click or scan EU-EC-10009374641 | | 2021-07-15 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental]) |
| **13969** | click or scan EU-EC-10009374552 | | 2021-07-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Coronary artery occlusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 13970 | click or scan EU-EC-10009374544 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13971 | click or scan EU-EC-10009374153 | | 2021-07-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Illness (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 13972 | click or scan EU-EC-10009373773 | | 2021-07-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 13973 | click or scan EU-EC-10009373512 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 13974 | click or scan EU-EC-10009373332 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| 13975 | click or scan EU-EC-10009373183 | | 2021-07-15 | Healthcare Professional | EEA | More than 85 Years | Female | Headache (n/a - Fatal - **Results in Death**, Disabling), Hemiparesis (n/a - Fatal - **Results in Death**, Disabling), Peripheral swelling (n/a - Fatal - **Results in Death**, Disabling), Thrombophlebitis (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13976 | click or scan EU-EC-10009372950 | | 2021-07-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 13977 | click or scan EU-EC-10009372761 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypokinesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyporeflexia (n/a - Unknown - Other Medically Important Condition), Hypotonia (n/a - Unknown - Other Medically Important Condition), Hypoventilation (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Quadriparesis (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory muscle weakness (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13978 | click or scan EU-EC-10009372669 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13979 | click or scan EU-EC-10009372665 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **13980** | click or scan EU-EC-10009372659 |  | 2021-07-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Activated partial thromboplastin time shortened (n/a - Unknown - ), Base excess increased (n/a - Unknown - ), Blood chloride increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Blood lactic acid increased (n/a - Unknown - ), Blood methaemoglobin present (n/a - Unknown - ), Blood potassium decreased (n/a - Unknown - ), Blood sodium increased (n/a - Unknown - ), Brain death (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - ), Carboxyhaemoglobin increased (n/a - Unknown - ), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ear pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eosinophil count decreased (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Gamma-glutamyltransferase increased (n/a - Unknown - ), Glomerular filtration rate decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immature granulocyte count increased (n/a - Unknown - ), Lymphocyte count decreased (n/a - Unknown - ), Meningitis pneumococcal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Monocyte count increased (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neutrophil count increased (n/a - Unknown - ), Nystagmus (n/a - Unknown - Caused/Prolonged Hospitalisation), Oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Otolithiasis (n/a - Unknown - Caused/Prolonged Hospitalisation), PCO2 increased (n/a - Unknown - ), PO2 increased (n/a - Unknown - ), Procalcitonin increased (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ), pH body fluid decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13981** | click or scan EU-EC-10009372182 |  | 2021-07-15 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **13982** | click or scan EU-EC-10009372177 |  | 2021-07-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Joint swelling (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **13983** | click or scan EU-EC-10009372004 |  | 2021-07-15 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Agitation (n/a - Unknown - ), Dementia (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **13984** | click or scan EU-EC-10009371957 |  | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Obstructive airways disorder (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **13985** | click or scan EU-EC-10009371945 |  | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Chronic kidney disease (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13986** | click or scan EU-EC-10009371434 |  | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Discoloured vomit (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**), Faeces discoloured (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown - ), Hypoglycaemia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 13987 | click or scan EU-EC-10009371181 | | 2021-07-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 13988 | click or scan EU-EC-10009370933 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 13989 | click or scan EU-EC-10009370864 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13990 | click or scan EU-EC-10009370696 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 13991 | click or scan EU-EC-10009370507 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Brain compression (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Snoring (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13992 | click or scan EU-EC-10009370301 | | 2021-07-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 13993 | click or scan EU-EC-10009370263 | | 2021-07-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (4d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown - More in ICSR]) |
| 13994 | click or scan EU-EC-10009370007 | | 2021-07-15 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 13995 | click or scan EU-EC-10009370005 | | 2021-07-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atypical pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 13996 | click or scan EU-EC-10009369740 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **13997** | click or scan EU-EC-10009369711 | | 2021-07-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Cyanosis (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **13998** | click or scan EU-EC-10009369036 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Compartment syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Lactic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **13999** | click or scan EU-EC-10009367414 | | 2021-07-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), [DIMENHYDRINATE, DIMENHYDRINATE BP] (I - n/a - n/a - [n/a - n/a - n/a]), [ONDANSETRON] (I - n/a - n/a - [n/a - n/a - n/a]) |
| **14000** | click or scan EU-EC-10009366978 | | 2021-07-14 | Healthcare Professional | EEA | 65-85 Years | Female | SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **14001** | click or scan EU-EC-10009366912 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Febrile infection (n/a - Unknown - Other Medically Important Condition), Osteomyelitis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**), Vascular device infection (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14002** | click or scan EU-EC-10009366717 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14003** | click or scan EU-EC-10009366564 | | 2021-07-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14004** | click or scan EU-EC-10009366422 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary artery occlusion (n/a - Fatal - **Results in Death**), Coronary artery stenosis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **14005** | click or scan EU-EC-10009366313 | | 2021-07-14 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14006** | click or scan EU-EC-10009365997 | | 2021-07-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Axillary pain (n/a - Fatal - **Results in Death**, Disabling), Condition aggravated (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**, Disabling), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**, Disabling), Lymphadenopathy (n/a - Fatal - **Results in Death**, Disabling), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14007** | click or scan EU-EC-10009365833 | | 2021-07-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Nasopharyngitis (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **14008** | click or scan EU-EC-10009365764 | | 2021-07-14 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **14009** | click or scan EU-EC-10009365598 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14010** | click or scan EU-EC-10009365551 | | 2021-07-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14011** | click or scan EU-EC-10009365541 | | 2021-07-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Arthralgia (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Haemorrhage (n/a - Unknown - Other Medically Important Condition), Renal disorder (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14012** | click or scan EU-EC-10009364849 | | 2021-07-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **14013** | click or scan EU-EC-10009364702 | | 2021-07-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14014** | click or scan EU-EC-10009364555 | | 2021-07-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Recovering/Resolving - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14015** | click or scan EU-EC-10009364404 | | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14016** | click or scan EU-EC-10009364337 | | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14017** | click or scan EU-EC-10009364261 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14018** | click or scan EU-EC-10009364260 |  | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral artery perforation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Off label use (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14019** | click or scan EU-EC-10009364257 |  | 2021-07-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Urine output decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14020** | click or scan EU-EC-10009364151 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dysstasia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14021** | click or scan EU-EC-10009363685 |  | 2021-07-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14022** | click or scan EU-EC-10009363681 |  | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Drowning (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14023** | click or scan EU-EC-10009363217 |  | 2021-07-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14024** | click or scan EU-EC-10009363174 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation), Vascular dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14025** | click or scan EU-EC-10009363171 |  | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14026** | click or scan EU-EC-10009363140 |  | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14027** | click or scan EU-EC-10009363083 |  | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**), Cerebrovascular accident (7d - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Venous thrombosis (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **14028** | click or scan EU-EC-10009362736 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14029** | click or scan EU-EC-10009362565 |  | 2021-07-14 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertensive crisis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Dose not changed - [n/a - 1 {DF} - Intramuscular]) |
| **14030** | click or scan EU-EC-10009362458 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dementia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (1d - Fatal - **Results in Death**), Hypophagia (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14031** | click or scan EU-EC-10009362037 |  | 2021-07-14 | Healthcare Professional | Non EEA | Not Specified | Male | Foetal heart rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **14032** | click or scan EU-EC-10009361839 |  | 2021-07-14 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **14033** | click or scan EU-EC-10009361760 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14034** | click or scan EU-EC-10009361577 |  | 2021-07-14 | Healthcare Professional | EEA | More than 85 Years | Male | Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Primary amyloidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **14035** | click or scan EU-EC-10009361560 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14036** | click or scan EU-EC-10009361039 |  | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Parkinson's disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14037 | click or scan EU-EC-10009360953 | | 2021-07-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14038 | click or scan EU-EC-10009360943 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia pneumococcal (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 14039 | click or scan EU-EC-10009360707 | | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Shock haemorrhagic (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 14040 | click or scan EU-EC-10009360571 | | 2021-07-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Atrioventricular block (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14041 | click or scan EU-EC-10009360334 | | 2021-07-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14042 | click or scan EU-EC-10009360299 | | 2021-07-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14043 | click or scan EU-EC-10009359226 | | 2021-07-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hospitalisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14044 | click or scan EU-EC-10009358999 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14045 | click or scan EU-EC-10009358882 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14046 | click or scan EU-EC-10009358881 | | 2021-07-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14047 | click or scan EU-EC-10009358469 | | 2021-07-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14048 | click or scan EU-EC-10009358409 | | 2021-07-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14049 | click or scan EU-EC-10009357157 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14050 | click or scan EU-EC-10009357032 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14051 | click or scan EU-EC-10009357023 | | 2021-07-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rheumatoid arthritis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14052 | click or scan EU-EC-10009356924 | | 2021-07-13 | Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14053 | click or scan EU-EC-10009356586 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14054 | click or scan EU-EC-10009356554 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoproliferative disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14055 | click or scan EU-EC-10009356334 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14056 | click or scan EU-EC-10009356288 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Areflexia (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Mydriasis (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulse absent (1d - Fatal - **Results in Death**), Pulseless electrical activity (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pupil fixed (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14057** | click or scan EU-EC-10009356088 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **14058** | click or scan EU-EC-10009356057 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Male | Infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - Intramuscular]) |
| **14059** | click or scan EU-EC-10009355963 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Heart rate irregular (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumocystis jirovecii pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), IMRALDI [ADALIMUMAB] (S - Rheumatoid arthritis - Unknown - [176d - 40mg - Subcutaneous]) |
| **14060** | click or scan EU-EC-10009355858 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Electroencephalogram abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypopnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Status epilepticus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14061** | click or scan EU-EC-10009355616 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **14062** | click or scan EU-EC-10009355570 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthma (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14063** | click or scan EU-EC-10009355525 | | 2021-07-13 | Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Purpura (n/a - Fatal - **Results in Death**), Rash macular (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14064** | click or scan EU-EC-10009355499 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14065 | click or scan EU-EC-10009355461 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14066 | click or scan EU-EC-10009355431 | | 2021-07-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Blindness unilateral (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in jaw (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subdural haematoma (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14067 | click or scan EU-EC-10009355360 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14068 | click or scan EU-EC-10009355125 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14069 | click or scan EU-EC-10009354465 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac disorder (59d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14070 | click or scan EU-EC-10009354210 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**), Mobility decreased (8d - Fatal - **Results in Death**), Peripheral swelling (8d - Fatal - **Results in Death**), Posture abnormal (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14071 | click or scan EU-EC-10009354133 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (2d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Dyspnoea (2d - Unknown - Caused/Prolonged Hospitalisation), Headache (2d - Unknown - Caused/Prolonged Hospitalisation), Nausea (2d - Unknown - Caused/Prolonged Hospitalisation), Vomiting (2d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14072 | click or scan EU-EC-10009354113 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Thrombotic cerebral infarction (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14073 | click or scan EU-EC-10009353965 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14074 | click or scan EU-EC-10009353362 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]), [COVID-19 VACCINE] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| 14075 | click or scan EU-EC-10009353348 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Chronic kidney disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14076 | click or scan EU-EC-10009353330 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (28d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**), Obesity (28d - Fatal - **Results in Death**), Respiratory failure (28d - Fatal - **Results in Death**, Other Medically Important Condition), Rheumatoid arthritis (28d - Fatal - **Results in Death**), Type 1 diabetes mellitus (28d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14077 | click or scan EU-EC-10009353168 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (47d - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Dementia (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Malnutrition (n/a - Fatal - **Results in Death**), Peripheral vascular disorder (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Squamous cell carcinoma of skin (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14078 | click or scan EU-EC-10009352998 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Upper gastrointestinal haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14079 | click or scan EU-EC-10009352373 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14080 | click or scan EU-EC-10009352333 | | 2021-07-13 | Healthcare Professional | EEA | 18-64 Years | Female | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14081 | click or scan EU-EC-10009352296 | | 2021-07-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 14082 | click or scan EU-EC-10009352288 | | 2021-07-13 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14083** | click or scan EU-EC-10009352282 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **14084** | click or scan EU-EC-10009352218 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **14085** | click or scan EU-EC-10009352168 | | 2021-07-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dementia Alzheimer's type (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **14086** | click or scan EU-EC-10009352016 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immediate post-injection reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| **14087** | click or scan EU-EC-10009351901 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), General physical health deterioration (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| **14088** | click or scan EU-EC-10009351837 | | 2021-07-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Hyperpyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pain in extremity (n/a - Unknown - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14089** | click or scan EU-EC-10009351326 | | 2021-07-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14090** | click or scan EU-EC-10009351251 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **14091** | click or scan EU-EC-10009350746 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depression (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Left ventricular failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malnutrition (n/a - Fatal - **Results in Death**), Toxic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14092** | click or scan EU-EC-10009350442 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Angiopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14093** | click or scan EU-EC-10009350133 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), COVID-19 (20d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14094** | click or scan EU-EC-10009350077 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **14095** | click or scan EU-EC-10009350034 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic skin ulcer (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral arterial occlusive disease (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral ischaemia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14096** | click or scan EU-EC-10009349958 | | 2021-07-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (0d - Fatal - **Results in Death**), Pulmonary artery thrombosis (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14097** | click or scan EU-EC-10009349957 | | 2021-07-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14098** | click or scan EU-EC-10009349951 | | 2021-07-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Basal ganglia infarction (n/a - Fatal - **Results in Death**), Cerebral endovascular aneurysm repair (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Electroencephalogram abnormal (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyelonephritis (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Tracheostomy (n/a - Fatal - **Results in Death**), Ventricular cisternostomy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **14099** | click or scan EU-EC-10009349932 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Oral]) |
| **14100** | click or scan EU-EC-10009349711 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14101** | click or scan EU-EC-10009349709 |  | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14102** | click or scan EU-EC-10009349395 |  | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14103** | click or scan EU-EC-10009349354 |  | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14104** | click or scan EU-EC-10009348920 |  | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14105** | click or scan EU-EC-10009348785 |  | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **14106** | click or scan EU-EC-10009348679 |  | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14107** | click or scan EU-EC-10009348587 |  | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **14108** | click or scan EU-EC-10009348533 |  | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| **14109** | click or scan EU-EC-10009348411 |  | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14110** | click or scan EU-EC-10009348329 |  | 2021-07-13 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14111 | click or scan EU-EC-10009348310 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14112 | click or scan EU-EC-10009348255 | | 2021-07-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14113 | click or scan EU-EC-10009348118 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypocoagulable state (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin ulcer (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [WARFARIN, WARFARIN SODIUM] (I - Mitral valve replacement - Unknown - [23y - 5mg - Oral]) |
| 14114 | click or scan EU-EC-10009347960 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14115 | click or scan EU-EC-10009347727 | | 2021-07-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac disorder (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14116 | click or scan EU-EC-10009347716 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14117 | click or scan EU-EC-10009347574 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14118 | click or scan EU-EC-10009347292 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14119 | click or scan EU-EC-10009347228 | | 2021-07-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Impaired work ability (n/a - Fatal - **Results in Death**), Injection site erythema (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14120 | click or scan EU-EC-10009347177 | | 2021-07-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14121 | click or scan EU-EC-10009347000 | | 2021-07-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14122 | click or scan EU-EC-10009346069 | | 2021-07-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Apnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14123 | click or scan EU-EC-10009345331 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - ), Myalgia (n/a - Recovered/Resolved - ), Pain (n/a - Unknown - ), Pruritus (n/a - Unknown - ), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14124 | click or scan EU-EC-10009345189 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14125 | click or scan EU-EC-10009345166 | | 2021-07-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14126 | click or scan EU-EC-10009345122 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14127 | click or scan EU-EC-10009345045 | | 2021-07-12 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 14128 | click or scan EU-EC-10009344969 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Injection site swelling (n/a - Fatal - **Results in Death**), Irritability (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14129 | click or scan EU-EC-10009344778 | | 2021-07-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14130 | click or scan EU-EC-10009344637 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Rectal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14131 | click or scan EU-EC-10009344593 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14132 | click or scan EU-EC-10009344580 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14133 | click or scan EU-EC-10009344576 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Incorrect route of product administration (n/a - Unknown - ), Viral infection (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 14134 | click or scan EU-EC-10009344492 | | 2021-07-12 | Healthcare Professional | EEA | 65-85 Years | Male | Epistaxis (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 14135 | click or scan EU-EC-10009344414 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14136 | click or scan EU-EC-10009344006 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal obstruction (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14137 | click or scan EU-EC-10009343966 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14138 | click or scan EU-EC-10009343272 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14139 | click or scan EU-EC-10009343049 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14140 | click or scan EU-EC-10009342934 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14141 | click or scan EU-EC-10009342858 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (1d - Fatal - **Results in Death**), Cardiac failure congestive (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Fatal - **Results in Death**), End stage renal disease (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (1d - Fatal - **Results in Death**), Sarcoidosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14142 | click or scan EU-EC-10009342851 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14143 | click or scan EU-EC-10009342848 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (67d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14144 | click or scan EU-EC-10009342822 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14145 | click or scan EU-EC-10009342621 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute myocardial infarction (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bandaemia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung consolidation (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14146 | click or scan EU-EC-10009342351 | | 2021-07-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14147 | click or scan EU-EC-10009342333 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Male | Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14148 | click or scan EU-EC-10009341877 | | 2021-07-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Recovered/Resolved - ), Cardiac death (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Fatigue (n/a - Recovered/Resolved - ), Head discomfort (n/a - Unknown - ), Headache (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14149 | click or scan EU-EC-10009341774 | | 2021-07-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14150 | click or scan EU-EC-10009341704 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14151 | click or scan EU-EC-10009341614 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14152 | click or scan EU-EC-10009341612 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14153 | click or scan EU-EC-10009341607 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Male | Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14154 | click or scan EU-EC-10009340640 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14155 | click or scan EU-EC-10009340590 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14156 | click or scan EU-EC-10009340560 | | 2021-07-12 | Healthcare Professional | EEA | More than 85 Years | Female | Lung disorder (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (S - Atrial fibrillation - Dose not changed - [n/a - 1 {DF} - Oral]) |
| 14157 | click or scan EU-EC-10009340521 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 14158 | click or scan EU-EC-10009340492 | | 2021-07-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 14159 | click or scan EU-EC-10009340406 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14160 | click or scan EU-EC-10009340348 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Fatal - **Results in Death**), Feeling abnormal (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14161 | click or scan EU-EC-10009340148 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (57d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14162 | click or scan EU-EC-10009340040 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Intracranial aneurysm (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14163 | click or scan EU-EC-10009339893 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14164 | click or scan EU-EC-10009339871 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apallic syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Autoimmune disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Back pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Contusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dialysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Discomfort (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyskinesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysstasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Electroencephalogram (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fine motor skill dysfunction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal tube insertion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Noninfective encephalitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal function test abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 14165 | click or scan EU-EC-10009339868 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Nucleic acid test (n/a - Fatal - **Results in Death**), Obesity (n/a - Fatal - **Results in Death**), Polymerase chain reaction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14166 | click or scan EU-EC-10009339737 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14167 | click or scan EU-EC-10009339560 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14168 | click or scan EU-EC-10009339546 | | 2021-07-12 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14169 | click or scan EU-EC-10009339539 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14170 | click or scan EU-EC-10009339244 | | 2021-07-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Acute respiratory failure (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inflammation (n/a - Unknown - Other Medically Important Condition), Injection site pain (n/a - Recovered/Resolved - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14171 | click or scan EU-EC-10009339062 | | 2021-07-12 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14172 | click or scan EU-EC-10009338717 | | 2021-07-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14173 | click or scan EU-EC-10009338580 | | 2021-07-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14174 | click or scan EU-EC-10009338543 | | 2021-07-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14175 | click or scan EU-EC-10009338518 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14176 | click or scan EU-EC-10009338458 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14177 | click or scan EU-EC-10009338403 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery disease (10d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diabetic nephropathy (10d - Fatal - **Results in Death**), End stage renal disease (10d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (10d - Fatal - **Results in Death**), Type 2 diabetes mellitus (10d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14178 | click or scan EU-EC-10009338210 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (1d - Fatal - **Results in Death**), Urinary tract infection (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14179 | click or scan EU-EC-10009337956 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14180 | click or scan EU-EC-10009337704 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14181 | click or scan EU-EC-10009337692 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Intracranial mass (2014d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14182 | click or scan EU-EC-10009337692 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Intracranial mass (2014d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14183 | click or scan EU-EC-10009337473 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14184 | click or scan EU-EC-10009336951 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - ), Cardiac failure (10d - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Haemoptysis (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Toothache (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14185 | click or scan EU-EC-10009336801 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14186** | click or scan EU-EC-10009336749 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14187** | click or scan EU-EC-10009336718 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14188** | click or scan EU-EC-10009336691 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular]) |
| **14189** | click or scan EU-EC-10009336429 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14190** | click or scan EU-EC-10009336428 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14191** | click or scan EU-EC-10009336176 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14192** | click or scan EU-EC-10009336092 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (14d - Fatal - **Results in Death**, Other Medically Important Condition), Chronic obstructive pulmonary disease (14d - Fatal - **Results in Death**), Condition aggravated (14d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14193** | click or scan EU-EC-10009335986 | | 2021-07-12 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **14194** | click or scan EU-EC-10009335786 | | 2021-07-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **14195** | click or scan EU-EC-10009335750 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14196** | click or scan EU-EC-10009335606 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14197** | click or scan EU-EC-10009335113 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cholangitis (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14198** | click or scan EU-EC-10009334766 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Vital functions abnormal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intradermal]) |
| **14199** | click or scan EU-EC-10009334619 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspepsia (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **14200** | click or scan EU-EC-10009334604 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Life Threatening), Product use issue (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [1d - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a]) |
| **14201** | click or scan EU-EC-10009334604 | | 2021-07-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Life Threatening), Product use issue (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [1d - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14202** | click or scan EU-EC-10009334480 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriosclerosis coronary artery (75d - Fatal - **Results in Death**), Asthenia (75d - Fatal - **Results in Death**), Bone pain (75d - Fatal - **Results in Death**), Chest pain (75d - Fatal - **Results in Death**), Condition aggravated (75d - Fatal - **Results in Death**), Cough (75d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (75d - Fatal - **Results in Death**), Feeling abnormal (75d - Fatal - **Results in Death**), Hypoglycaemia (75d - Fatal - **Results in Death**), Lethargy (75d - Fatal - **Results in Death**), Myocardial infarction (75d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (75d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (75d - Fatal - **Results in Death**), Resuscitation (75d - Fatal - **Results in Death**), Rhinorrhoea (75d - Fatal - **Results in Death**), Seizure (75d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14203** | click or scan EU-EC-10009334421 | | 2021-07-12 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14204** | click or scan EU-EC-10009334151 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Unknown - ), Hyponatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14205** | click or scan EU-EC-10009333918 | | 2021-07-12 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **14206** | click or scan EU-EC-10009333788 | | 2021-07-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14207** | click or scan EU-EC-10009333173 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14208** | click or scan EU-EC-10009333075 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Blood pressure decreased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14209** | click or scan EU-EC-10009332904 | | 2021-07-12 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14210** | click or scan EU-EC-10009332838 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14211 | click or scan EU-EC-10009332814 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14212 | click or scan EU-EC-10009332806 | | 2021-07-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14213 | click or scan EU-EC-10009332768 | | 2021-07-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14214 | click or scan EU-EC-10009330998 | | 2021-07-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14215 | click or scan EU-EC-10009330570 | | 2021-07-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 14216 | click or scan EU-EC-10009330325 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14217 | click or scan EU-EC-10009330072 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Leukaemia (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14218 | click or scan EU-EC-10009329965 | | 2021-07-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain injury (n/a - Unknown - **Results in Death**), Cardiac arrest (n/a - Recovered/Resolved - **Results in Death**), Diarrhoea (n/a - Unknown - **Results in Death**), Pulmonary embolism (2d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14219 | click or scan EU-EC-10009329837 | | 2021-07-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 14220 | click or scan EU-EC-10009329824 | | 2021-07-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (6d - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14221 | click or scan EU-EC-10009329556 | | 2021-07-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (1d - Fatal - **Results in Death**), Sedation (n/a - Unknown - **Results in Death**), Vaccination site haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a]) |
| 14222 | click or scan EU-EC-10009329542 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (1d - Recovered/Resolved - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Influenza like illness (n/a - Unknown - **Results in Death**), Ocular discomfort (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 14223 | click or scan EU-EC-10009329537 | | 2021-07-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14224 | click or scan EU-EC-10009329488 | | 2021-07-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14225 | click or scan EU-EC-10009329170 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - n/a]) |
| 14226 | click or scan EU-EC-10009329155 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Deep vein thrombosis (7d - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Feeling hot (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Pneumonia (7d - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14227 | click or scan EU-EC-10009328575 | | 2021-07-10 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Thrombosis in device (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14228 | click or scan EU-EC-10009328522 | | 2021-07-10 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14229 | click or scan EU-EC-10009328176 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (57d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14230 | click or scan EU-EC-10009328004 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhage intracranial (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 14231 | click or scan EU-EC-10009327979 | | 2021-07-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14232 | click or scan EU-EC-10009327866 | | 2021-07-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (68d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14233 | click or scan EU-EC-10009327736 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood viscosity increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14234 | click or scan EU-EC-10009327722 | | 2021-07-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14235 | click or scan EU-EC-10009327693 | | 2021-07-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (24h - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (24h - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (24h - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14236 | click or scan EU-EC-10009327657 | | 2021-07-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14237 | click or scan EU-EC-10009326550 | | 2021-07-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14238 | click or scan EU-EC-10009326516 | | 2021-07-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14239 | click or scan EU-EC-10009326437 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14240 | click or scan EU-EC-10009326352 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Embolism venous (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 14241 | click or scan EU-EC-10009326204 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14242** | click or scan EU-EC-10009326201 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Unknown - ), Head discomfort (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14243** | click or scan EU-EC-10009325833 | | 2021-07-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Accelerated hypertension (n/a - Fatal - **Results in Death**), Cholecystitis acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14244** | click or scan EU-EC-10009325726 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14245** | click or scan EU-EC-10009325615 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - ), Atrial fibrillation (n/a - Unknown - ), Epistaxis (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Hypotension (n/a - Unknown - ), International normalised ratio increased (n/a - Unknown - ), Subdural haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14246** | click or scan EU-EC-10009325584 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14247** | click or scan EU-EC-10009325577 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Blood glucose decreased (n/a - Recovering/Resolving - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14248** | click or scan EU-EC-10009325551 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Anxiety (n/a - Unknown - ), Atrial flutter (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Cystitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - ), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**), Malaise (4d - Recovering/Resolving - ), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Supraventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14249** | click or scan EU-EC-10009325532 | | 2021-07-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **14250** | click or scan EU-EC-10009325253 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14251 | click or scan EU-EC-10009325185 | | 2021-07-09 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonitis (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), KEYTRUDA 25 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION [PEMBROLIZUMAB] (S - Neuroendocrine tumour - Drug withdrawn - [37d - n/a - Intravenous (not otherwise specified)]) |
| 14252 | click or scan EU-EC-10009325110 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Unknown - Other Medically Important Condition), Agonal respiration (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradycardia (n/a - Unknown - ), Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - ), Hypoxia (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Mydriasis (2d - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14253 | click or scan EU-EC-10009324518 | | 2021-07-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14254 | click or scan EU-EC-10009324399 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14255 | click or scan EU-EC-10009324389 | | 2021-07-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14256 | click or scan EU-EC-10009324379 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Brain hypoxia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic kidney disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Extrasystoles (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Hypertension (n/a - Fatal - **Results in Death**), Musculoskeletal chest pain (n/a - Unknown - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14257 | click or scan EU-EC-10009324278 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Laryngeal oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14258 | click or scan EU-EC-10009324233 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14259 | click or scan EU-EC-10009324184 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14260 | click or scan EU-EC-10009324160 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Intraventricular haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14261 | click or scan EU-EC-10009323932 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14262 | click or scan EU-EC-10009323838 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**), Condition aggravated (15d - Not Recovered/Not Resolved - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pneumonia (15d - Not Recovered/Not Resolved - ), Somnolence (15d - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14263 | click or scan EU-EC-10009323758 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Life Threatening), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14264 | click or scan EU-EC-10009323438 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14265 | click or scan EU-EC-10009323128 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14266 | click or scan EU-EC-10009323126 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14267 | click or scan EU-EC-10009323124 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14268 | click or scan EU-EC-10009322960 | | 2021-07-09 | Healthcare Professional | EEA | 65-85 Years | Female | Anti-neutrophil cytoplasmic antibody positive vasculitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Unknown - Life Threatening, Other Medically Important Condition), Discomfort (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Glomerulonephritis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung consolidation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle atrophy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - ), Polyneuropathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14269 | click or scan EU-EC-10009322764 | | 2021-07-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14270 | click or scan EU-EC-10009322463 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14271 | click or scan EU-EC-10009322442 | | 2021-07-09 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14272 | click or scan EU-EC-10009322130 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [ACENOCOUMAROL] (S - Thrombosis - Drug withdrawn - [n/a - 1 {DF} - n/a]) |
| 14273 | click or scan EU-EC-10009322013 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14274 | click or scan EU-EC-10009321838 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14275 | click or scan EU-EC-10009321836 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14276 | click or scan EU-EC-10009321816 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Dose not changed - [n/a - n/a - Intramuscular]), [ATENOLOL, ATENOLOL BP] (S - Hypertension - Dose not changed - [n/a - n/a - n/a]) |
| 14277 | click or scan EU-EC-10009321753 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14278 | click or scan EU-EC-10009321738 | | 2021-07-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14279 | click or scan EU-EC-10009321724 | | 2021-07-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Status epilepticus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14280 | click or scan EU-EC-10009321645 | | 2021-07-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14281 | click or scan EU-EC-10009321638 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Coagulopathy (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14282 | click or scan EU-EC-10009321628 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Language disorder (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14283 | click or scan EU-EC-10009321624 | | 2021-07-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14284 | click or scan EU-EC-10009320927 | | 2021-07-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular]) |
| 14285 | click or scan EU-EC-10009320925 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14286 | click or scan EU-EC-10009320916 | | 2021-07-09 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Subcutaneous]) |
| 14287 | click or scan EU-EC-10009320848 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14288 | click or scan EU-EC-10009320805 | | 2021-07-09 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 14289 | click or scan EU-EC-10009320790 | | 2021-07-09 | Healthcare Professional | EEA | More than 85 Years | Male | Epilepsy (1d - Recovered/Resolved - Life Threatening), Status epilepticus (57d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 14290 | click or scan EU-EC-10009320744 | | 2021-07-09 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14291** | click or scan EU-EC-10009320183 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14292** | click or scan EU-EC-10009319961 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14293** | click or scan EU-EC-10009319951 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14294** | click or scan EU-EC-10009319864 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14295** | click or scan EU-EC-10009319858 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14296** | click or scan EU-EC-10009319589 | | 2021-07-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Agitation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Endocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral swelling (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Dose not changed - [n/a - n/a - Intramuscular]) |
| **14297** | click or scan EU-EC-10009319356 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14298** | click or scan EU-EC-10009319271 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Immunisation reaction (2d - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **14299** | click or scan EU-EC-10009319264 | | 2021-07-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14300** | click or scan EU-EC-10009319219 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Ventricular fibrillation (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14301 | click or scan EU-EC-10009319194 | | 2021-07-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14302 | click or scan EU-EC-10009318500 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14303 | click or scan EU-EC-10009318498 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14304 | click or scan EU-EC-10009318484 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14305 | click or scan EU-EC-10009318438 | | 2021-07-09 | Healthcare Professional | EEA | More than 85 Years | Male | Capillary leak syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Eating disorder (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Swelling (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14306 | click or scan EU-EC-10009318427 | | 2021-07-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dehydration (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14307 | click or scan EU-EC-10009318422 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14308 | click or scan EU-EC-10009318365 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Unknown - Caused/Prolonged Hospitalisation), Anosmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hospitalisation (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Micturition disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - ), Weight decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14309 | click or scan EU-EC-10009318173 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14310 | click or scan EU-EC-10009318047 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Capillary leak syndrome (n/a - Fatal - **Results in Death**), Haemoglobinaemia (n/a - Unknown - ), Hypoalbuminaemia (n/a - Unknown - ), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Shock (n/a - Not Recovered/Not Resolved - Life Threatening), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14311 | click or scan EU-EC-10009317196 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adenocarcinoma of colon (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14312 | click or scan EU-EC-10009316663 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14313 | click or scan EU-EC-10009316593 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14314 | click or scan EU-EC-10009316044 | | 2021-07-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14315 | click or scan EU-EC-10009315795 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Chills (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Ear pain (n/a - Unknown - ), Hypotension (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rhinorrhoea (n/a - Unknown - ), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14316 | click or scan EU-EC-10009315736 | | 2021-07-09 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14317 | click or scan EU-EC-10009315612 | | 2021-07-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14318 | click or scan EU-EC-10009315582 | | 2021-07-09 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 14319 | click or scan EU-EC-10009315390 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14320 | click or scan EU-EC-10009315097 | | 2021-07-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (0d - Fatal - **Results in Death**, Life Threatening), Ischaemic cerebral infarction (0d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 14321 | click or scan EU-EC-10009314988 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14322 | click or scan EU-EC-10009314550 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14323 | click or scan EU-EC-10009314542 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14324 | click or scan EU-EC-10009314385 | | 2021-07-09 | Non Healthcare Professional | EEA | Not Specified | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14325 | click or scan EU-EC-10009313931 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14326 | click or scan EU-EC-10009313634 | | 2021-07-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14327 | click or scan EU-EC-10009313619 | | 2021-07-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14328 | click or scan EU-EC-10009313322 | | 2021-07-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14329 | click or scan EU-EC-10009312715 | | 2021-07-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Restlessness (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14330 | click or scan EU-EC-10009312562 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pancreatitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14331 | click or scan EU-EC-10009312029 | | 2021-07-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14332 | click or scan EU-EC-10009311603 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anaemia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colitis ischaemic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Constipation (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery disease (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epigastric discomfort (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling cold (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Livedo reticularis (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14333 | click or scan EU-EC-10009311547 | | 2021-07-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - ), Muscle spasms (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14334 | click or scan EU-EC-10009311124 | | 2021-07-08 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14335 | click or scan EU-EC-10009311013 | | 2021-07-08 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14336 | click or scan EU-EC-10009310806 | | 2021-07-08 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14337 | click or scan EU-EC-10009310688 | | 2021-07-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14338 | click or scan EU-EC-10009310339 | | 2021-07-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14339 | click or scan EU-EC-10009310222 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Unknown - ), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Traumatic intracranial haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14340 | click or scan EU-EC-10009309992 | | 2021-07-08 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (10d - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14341 | click or scan EU-EC-10009309974 | | 2021-07-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**, Life Threatening), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14342 | click or scan EU-EC-10009309901 | | 2021-07-08 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 14343 | click or scan EU-EC-10009309631 | | 2021-07-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14344 | click or scan EU-EC-10009309566 | | 2021-07-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hospice care (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14345 | click or scan EU-EC-10009308905 | | 2021-07-08 | Healthcare Professional | EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14346 | click or scan EU-EC-10009308741 | | 2021-07-08 | Healthcare Professional | EEA | 18-64 Years | Female | Brain death (3d - Fatal - **Results in Death**), Cardiac death (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14347 | click or scan EU-EC-10009308194 | | 2021-07-08 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14348 | click or scan EU-EC-10009307873 | | 2021-07-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Language disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [SERTRALINE] (S - n/a - Dose not changed - [n/a - 2 {DF} - Oral]), [VALPROMIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 600mg - Oral]) |
| 14349 | click or scan EU-EC-10009307793 | | 2021-07-08 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14350 | click or scan EU-EC-10009307674 | | 2021-07-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .6mL - Intramuscular]) |
| 14351 | click or scan EU-EC-10009307599 | | 2021-07-08 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 14352 | click or scan EU-EC-10009307597 | | 2021-07-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14353 | click or scan EU-EC-10009307578 | | 2021-07-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | Brain injury (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Enteritis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14354 | click or scan EU-EC-10009307423 | | 2021-07-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Brain compression (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vertigo (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 14355 | click or scan EU-EC-10009307236 | | 2021-07-08 | Healthcare Professional | EEA | Not Specified | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Disturbance in attention (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14356 | click or scan EU-EC-10009307178 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Iliac artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paranoia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral coldness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Refusal of treatment by patient (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal infarct (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin discolouration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14357 | click or scan EU-EC-10009306580 | | 2021-07-08 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic failure (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ocular icterus (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14358** | click or scan EU-EC-10009306244 | | 2021-07-08 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14359** | click or scan EU-EC-10009305959 | | 2021-07-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **14360** | click or scan EU-EC-10009305858 | | 2021-07-08 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14361** | click or scan EU-EC-10009305837 | | 2021-07-08 | Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14362** | click or scan EU-EC-10009305723 | | 2021-07-08 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14363** | click or scan EU-EC-10009305713 | | 2021-07-08 | Healthcare Professional | EEA | 65-85 Years | Female | Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mesenteric haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14364** | click or scan EU-EC-10009305463 | | 2021-07-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14365** | click or scan EU-EC-10009305427 | | 2021-07-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Lip swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Panic attack (n/a - Recovered/Resolved - ), Pharyngeal oedema (n/a - Recovered/Resolved - Other Medically Important Condition), Stevens-Johnson syndrome (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14366** | click or scan EU-EC-10009305425 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infective myositis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14367 | click or scan EU-EC-10009305419 | | 2021-07-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14368 | click or scan EU-EC-10009305156 | | 2021-07-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14369 | click or scan EU-EC-10009303024 | | 2021-07-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14370 | click or scan EU-EC-10009302872 | | 2021-07-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 14371 | click or scan EU-EC-10009302582 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colitis ischaemic (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (13d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ejection fraction decreased (13d - Fatal - **Results in Death**), Ischaemic cardiomyopathy (13d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (13d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 14372 | click or scan EU-EC-10009302495 | | 2021-07-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Continuous haemodiafiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic steatosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung assist device therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Right ventricular dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombectomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Withdrawal of life support (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14373 | click or scan EU-EC-10009301981 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14374 | click or scan EU-EC-10009301959 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14375 | click or scan EU-EC-10009301869 | | 2021-07-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Muscle fatigue (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14376 | click or scan EU-EC-10009301853 | | 2021-07-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hospitalisation (4h - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14377 | click or scan EU-EC-10009301677 | | 2021-07-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain upper (10d - Fatal - **Results in Death**), Death (10d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (10d - Fatal - **Results in Death**), Feeling abnormal (10d - Fatal - **Results in Death**), Vomiting (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14378 | click or scan EU-EC-10009301658 | | 2021-07-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14379 | click or scan EU-EC-10009301228 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 14380 | click or scan EU-EC-10009300922 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14381 | click or scan EU-EC-10009300741 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14382 | click or scan EU-EC-10009300362 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14383 | click or scan EU-EC-10009300360 | | 2021-07-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14384 | click or scan EU-EC-10009300328 | | 2021-07-08 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Embolism venous (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14385 | click or scan EU-EC-10009300327 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Anaphylactic reaction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14386 | click or scan EU-EC-10009300209 | | 2021-07-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**), Hepatic vascular thrombosis (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14387 | click or scan EU-EC-10009299738 | | 2021-07-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Intentional dose omission (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14388 | click or scan EU-EC-10009299405 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aspiration (30d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hiatus hernia (30d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation abnormal (30d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (30d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14389 | click or scan EU-EC-10009297923 | | 2021-07-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (10d - Fatal - **Results in Death**), Abdominal pain (10d - Fatal - **Results in Death**), Arteriosclerosis (10d - Fatal - **Results in Death**), Bronchial irritation (10d - Fatal - **Results in Death**), Coronary artery disease (10d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (10d - Fatal - **Results in Death**), Emphysema (10d - Fatal - **Results in Death**), Enteritis (10d - Fatal - **Results in Death**), Eosinophilia (10d - Fatal - **Results in Death**), Hypertension (10d - Fatal - **Results in Death**), Myocardial fibrosis (10d - Fatal - **Results in Death**), Myocarditis (10d - Fatal - **Results in Death**, Other Medically Important Condition), Oedema (10d - Fatal - **Results in Death**), Unresponsive to stimuli (10d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14390 | click or scan EU-EC-10009298981 | | 2021-07-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14391 | click or scan EU-EC-10009298767 | | 2021-07-07 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14392 | click or scan EU-EC-10009298567 | | 2021-07-07 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Epistaxis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14393** | click or scan EU-EC-10009297915 | | 2021-07-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Aspiration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Haemoptysis (n/a - Unknown - ), Hypersomnia (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Throat irritation (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [MENTHOL, METHYL SALICYLATE] (S - Product used for unknown indication - n/a - [n/a - 1 {DF} - Unknown]) |
| **14394** | click or scan EU-EC-10009297774 | | 2021-07-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Body temperature (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Coagulation time shortened (n/a - Unknown - ), Contusion (n/a - Unknown - ), Costovertebral angle tenderness (n/a - Unknown - ), Flank pain (n/a - Unknown - ), Haemorrhage (n/a - Unknown - Other Medically Important Condition), Limb discomfort (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Vasculitis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14395** | click or scan EU-EC-10009296869 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14396** | click or scan EU-EC-10009296844 | | 2021-07-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14397** | click or scan EU-EC-10009296546 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Deep vein thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (3d - Fatal - **Results in Death**), Thrombocytopenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombophlebitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | RIVAROXABAN [RIVAROXABAN] (I - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]), [DICLOFENAC SODIUM] (I - n/a - n/a - [n/a - n/a - n/a]), [DIOSMIN, HESPERIDIN] (I - n/a - n/a - [n/a - n/a - n/a]) |
| **14398** | click or scan EU-EC-10009296544 | | 2021-07-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Headache (n/a - Unknown - ), Jugular vein thrombosis (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Transverse sinus thrombosis (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14399** | click or scan EU-EC-10009296282 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14400** | click or scan EU-EC-10009296210 | | 2021-07-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14401** | click or scan EU-EC-10009295926 | | 2021-07-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14402** | click or scan EU-EC-10009295838 | | 2021-07-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Abdominal distension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vitamin K (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Volume blood decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14403** | click or scan EU-EC-10009295819 | | 2021-07-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sarcoidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14404** | click or scan EU-EC-10009295614 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14405** | click or scan EU-EC-10009295529 | | 2021-07-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dependence on respirator (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14406** | click or scan EU-EC-10009295455 | | 2021-07-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14407** | click or scan EU-EC-10009294740 | | 2021-07-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14408** | click or scan EU-EC-10009294252 | | 2021-07-07 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14409** | click or scan EU-EC-10009294251 | | 2021-07-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **14410** | click or scan EU-EC-10009294250 | | 2021-07-07 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14411 | click or scan EU-EC-10009293711 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (12h - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14412 | click or scan EU-EC-10009293254 | | 2021-07-07 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14413 | click or scan EU-EC-10009293131 | | 2021-07-07 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1 {DF} - Intramuscular]) |
| 14414 | click or scan EU-EC-10009292997 | | 2021-07-07 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 14415 | click or scan EU-EC-10009292605 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Facial asymmetry (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Foaming at mouth (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14416 | click or scan EU-EC-10009291876 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Contusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14417 | click or scan EU-EC-10009291582 | | 2021-07-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (18h - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14418 | click or scan EU-EC-10009290401 | | 2021-07-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Localised infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wound necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), NON SPECIFIED ANTIBIOTICA [NOT AVAILABLE] (S - Localised infection - Dose not changed - [n/a - n/a - n/a]) |
| 14419 | click or scan EU-EC-10009290143 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hyperhidrosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14420 | click or scan EU-EC-10009289645 | | 2021-07-07 | Healthcare Professional | EEA | 18-64 Years | Female | Hypoglycaemia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pupils unequal (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14421 | click or scan EU-EC-10009289294 | | 2021-07-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14422 | click or scan EU-EC-10009289037 | | 2021-07-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**), Injection site inflammation (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Injection site warmth (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14423 | click or scan EU-EC-10009288758 | | 2021-07-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anuria (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Liver disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14424 | click or scan EU-EC-10009288055 | | 2021-07-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14425 | click or scan EU-EC-10009288048 | | 2021-07-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Discomfort (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14426 | click or scan EU-EC-10009287427 | | 2021-07-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Amnesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immobile (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Incoherent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin exfoliation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14427 | click or scan EU-EC-10009287390 | | 2021-07-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Recovered/Resolved - ) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - n/a]) |
| 14428 | click or scan EU-EC-10009287084 | | 2021-07-07 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dependence on oxygen therapy (n/a - Unknown - Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Superinfection bacterial (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 14429 | click or scan EU-EC-10009286463 | | 2021-07-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14430 | click or scan EU-EC-10009286462 | | 2021-07-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cavernous sinus thrombosis (n/a - Fatal - **Results in Death**), Cerebral haematoma (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Photophobia (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14431** | click or scan EU-EC-10009286117 | | 2021-07-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Confusional state (2mo - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dysphagia (2mo - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (1d - Recovered/Resolved - ), Hemiplegia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Motor dysfunction (2mo - Not Recovered/Not Resolved - Other Medically Important Condition), Prion disease (n/a - Unknown - Life Threatening), Speech disorder (2mo - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14432** | click or scan EU-EC-10009286087 | | 2021-07-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14433** | click or scan EU-EC-10009286031 | | 2021-07-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory rate decreased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14434** | click or scan EU-EC-10009285883 | | 2021-07-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Illness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14435** | click or scan EU-EC-10009285529 | | 2021-07-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (66d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pruritus (66d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14436** | click or scan EU-EC-10009285376 | | 2021-07-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14437** | click or scan EU-EC-10009285318 | | 2021-07-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14438** | click or scan EU-EC-10009285151 | | 2021-07-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14439** | click or scan EU-EC-10009285042 | | 2021-07-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | B-cell lymphoma (106d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (106d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (106d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoma (106d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (106d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14440** | click or scan EU-EC-10009284897 | | 2021-07-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14441** | click or scan EU-EC-10009284156 |  | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **14442** | click or scan EU-EC-10009284076 |  | 2021-07-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation, Prophylaxis - Not applicable - [1d - n/a - n/a]) |
| **14443** | click or scan EU-EC-10009283783 |  | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Female | Dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (5d - Recovered/Resolved - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **14444** | click or scan EU-EC-10009283780 |  | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**), Headache (3d - Unknown - **Results in Death**), Muscle spasms (3d - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14445** | click or scan EU-EC-10009283643 |  | 2021-07-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - n/a - n/a - [n/a - n/a - n/a]) |
| **14446** | click or scan EU-EC-10009283242 |  | 2021-07-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardiac ablation (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14447** | click or scan EU-EC-10009283122 |  | 2021-07-06 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Hot flush (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14448** | click or scan EU-EC-10009282314 |  | 2021-07-06 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **14449** | click or scan EU-EC-10009282118 |  | 2021-07-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Candida sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epstein-Barr viraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14450** | click or scan EU-EC-10009281957 |  | 2021-07-06 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14451 | click or scan EU-EC-10009280856 |  | 2021-07-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic cytolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 14452 | click or scan EU-EC-10009280698 |  | 2021-07-06 | Healthcare Professional | EEA | 18-64 Years | Male | Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**), Tonic clonic movements (n/a - Recovered/Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14453 | click or scan EU-EC-10009280671 |  | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Female | Meningoradiculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 14454 | click or scan EU-EC-10009280667 |  | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14455 | click or scan EU-EC-10009280642 |  | 2021-07-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal discomfort (25d - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**), Diarrhoea (19d - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (19d - Fatal - **Results in Death**), Malaise (25d - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14456 | click or scan EU-EC-10009280427 |  | 2021-07-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 14457 | click or scan EU-EC-10009280334 |  | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14458 | click or scan EU-EC-10009280090 |  | 2021-07-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Other Medically Important Condition), Night sweats (n/a - Unknown - Caused/Prolonged Hospitalisation), Red blood cell sedimentation rate increased (n/a - Unknown - ), Serum ferritin increased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14459 | click or scan EU-EC-10009279955 |  | 2021-07-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14460 | click or scan EU-EC-10009279907 |  | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14461 | click or scan EU-EC-10009279663 | | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14462 | click or scan EU-EC-10009279540 | | 2021-07-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14463 | click or scan EU-EC-10009279537 | | 2021-07-06 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14464 | click or scan EU-EC-10009279536 | | 2021-07-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14465 | click or scan EU-EC-10009279400 | | 2021-07-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Peripheral vascular disorder (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14466 | click or scan EU-EC-10009279386 | | 2021-07-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14467 | click or scan EU-EC-10009278752 | | 2021-07-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product dose omission issue (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14468 | click or scan EU-EC-10009278661 | | 2021-07-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14469 | click or scan EU-EC-10009278467 | | 2021-07-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoaesthesia oral (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14470 | click or scan EU-EC-10009277769 | | 2021-07-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14471 | click or scan EU-EC-10009277764 | | 2021-07-06 | Healthcare Professional | EEA | 65-85 Years | Male | Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14472 | click or scan EU-EC-10009277138 | | 2021-07-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14473 | click or scan EU-EC-10009277005 | | 2021-07-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Critical illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14474 | click or scan EU-EC-10009276427 | | 2021-07-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (7d - Recovered/Resolved - ), Malaise (7d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14475 | click or scan EU-EC-10009276114 | | 2021-07-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Brain oedema (n/a - Unknown - Other Medically Important Condition), Cerebral thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrolyte imbalance (n/a - Unknown - Other Medically Important Condition), Gastrointestinal obstruction (n/a - Unknown - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Renal disorder (n/a - Unknown - Other Medically Important Condition), Rib fracture (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Sternal fracture (n/a - Unknown - Other Medically Important Condition), Thyroid mass (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14476 | click or scan EU-EC-10009275381 | | 2021-07-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Completed suicide (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Tinnitus (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14477 | click or scan EU-EC-10009273588 | | 2021-07-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dry mouth (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Thirst (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14478 | click or scan EU-EC-10009273470 | | 2021-07-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Resolved - ), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14479 | click or scan EU-EC-10009272819 | | 2021-07-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Recovered/Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14480 | click or scan EU-EC-10009272795 | | 2021-07-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaphylactic reaction (8h - Recovered/Resolved With Sequelae - Life Threatening, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14481 | click or scan EU-EC-10009272772 | | 2021-07-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Coronavirus test positive (n/a - Unknown - ), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14482 | click or scan EU-EC-10009272770 | | 2021-07-06 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 14483 | click or scan EU-EC-10009271350 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14484 | click or scan EU-EC-10009271267 | | 2021-07-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14485 | click or scan EU-EC-10009270794 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic dilatation (n/a - Fatal - **Results in Death**), Fatigue (3d - Recovered/Resolved - ), Injection site discomfort (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14486 | click or scan EU-EC-10009269865 | | 2021-07-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14487 | click or scan EU-EC-10009269720 | | 2021-07-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14488 | click or scan EU-EC-10009269645 | | 2021-07-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Disease recurrence (n/a - Unknown - Life Threatening), Myocardial infarction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Paraesthesia (n/a - Unknown - Life Threatening), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14489 | click or scan EU-EC-10009269248 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14490 | click or scan EU-EC-10009268855 | | 2021-07-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14491 | click or scan EU-EC-10009268353 | | 2021-07-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14492 | click or scan EU-EC-10009268207 | | 2021-07-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Unknown - ), Cough (n/a - Unknown - ), Hepatorenal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Systemic candida (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Upper respiratory tract infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14493 | click or scan EU-EC-10009267329 | | 2021-07-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Ascites (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Coronary artery stenosis (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14494 | click or scan EU-EC-10009266965 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14495 | click or scan EU-EC-10009265901 | | 2021-07-05 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14496 | click or scan EU-EC-10009265575 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14497 | click or scan EU-EC-10009265499 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14498 | click or scan EU-EC-10009265486 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Male | Ataxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 14499 | click or scan EU-EC-10009265485 | | 2021-07-05 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 14500 | click or scan EU-EC-10009265483 | | 2021-07-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebellar haematoma (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [ENOXAPARIN, ENOXAPARIN SODIUM] (S - Anticoagulant therapy - Drug withdrawn - [255d - .4mL - Subdermal]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14501 | click or scan EU-EC-10009265448 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [41d - n/a - Intramuscular]) |
| 14502 | click or scan EU-EC-10009265415 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14503 | click or scan EU-EC-10009265081 | | 2021-07-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14504 | click or scan EU-EC-10009264165 | | 2021-07-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14505 | click or scan EU-EC-10009263453 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14506 | click or scan EU-EC-10009263199 | | 2021-07-05 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14507 | click or scan EU-EC-10009262837 | | 2021-07-05 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14508 | click or scan EU-EC-10009261898 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14509 | click or scan EU-EC-10009261893 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14510 | click or scan EU-EC-10009261820 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14511 | click or scan EU-EC-10009261739 | | 2021-07-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Angina pectoris (n/a - Not Recovered/Not Resolved - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14512 | click or scan EU-EC-10009261735 | | 2021-07-05 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14513 | click or scan EU-EC-10009261731 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14514 | click or scan EU-EC-10009261723 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14515 | click or scan EU-EC-10009261484 | | 2021-07-05 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Stupor (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14516 | click or scan EU-EC-10009261115 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14517 | click or scan EU-EC-10009260947 | | 2021-07-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14518 | click or scan EU-EC-10009260749 | | 2021-07-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14519 | click or scan EU-EC-10009260452 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14520 | click or scan EU-EC-10009260446 | | 2021-07-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14521 | click or scan EU-EC-10009257735 | | 2021-07-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14522 | click or scan EU-EC-10009256506 | | 2021-07-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14523 | click or scan EU-EC-10009256323 | | 2021-07-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14524 | click or scan EU-EC-10009255692 | | 2021-07-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14525 | click or scan EU-EC-10009255635 | | 2021-07-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14526 | click or scan EU-EC-10009255617 | | 2021-07-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 14527 | click or scan EU-EC-10009255614 | | 2021-07-04 | Healthcare Professional | EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14528 | click or scan EU-EC-10009255579 | | 2021-07-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Exercise electrocardiogram abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 14529 | click or scan EU-EC-10009255493 | | 2021-07-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14530 | click or scan EU-EC-10009255467 | | 2021-07-04 | Healthcare Professional | EEA | 65-85 Years | Female | Bladder catheterisation (n/a - Not Recovered/Not Resolved - ), Dehydration (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Urinary retention (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14531 | click or scan EU-EC-10009253420 | | 2021-07-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14532 | click or scan EU-EC-10009253313 | | 2021-07-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14533 | click or scan EU-EC-10009253143 |  | 2021-07-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14534 | click or scan EU-EC-10009252947 |  | 2021-07-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14535 | click or scan EU-EC-10009252715 |  | 2021-07-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - **Results in Death**), Cough (n/a - Unknown - **Results in Death**), Meningitis pneumococcal (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [30d - n/a - Intramuscular]) |
| 14536 | click or scan EU-EC-10009252691 |  | 2021-07-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14537 | click or scan EU-EC-10009252683 |  | 2021-07-03 | Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14538 | click or scan EU-EC-10009252674 |  | 2021-07-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**), Subdural haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14539 | click or scan EU-EC-10009252540 |  | 2021-07-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14540 | click or scan EU-EC-10009252302 |  | 2021-07-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14541 | click or scan EU-EC-10009252289 |  | 2021-07-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Gastric haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14542 | click or scan EU-EC-10009252253 |  | 2021-07-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Decreased appetite (n/a - Unknown - **Results in Death**, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14543 | click or scan EU-EC-10009252203 | | 2021-07-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Unknown - **Results in Death**), Haemorrhage intracranial (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Thrombocytopenia (8d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14544 | click or scan EU-EC-10009251797 | | 2021-07-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hyperhidrosis (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14545 | click or scan EU-EC-10009251791 | | 2021-07-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemodynamic instability (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Hydrocephalus (n/a - Unknown - **Results in Death**), Mydriasis (n/a - Unknown - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**), Pupil fixed (n/a - Unknown - **Results in Death**), Repetitive strain injury (n/a - Unknown - **Results in Death**), Respiration abnormal (n/a - Unknown - **Results in Death**), Subarachnoid haemorrhage (1d - Fatal - **Results in Death**), Tinnitus (n/a - Unknown - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 14546 | click or scan EU-EC-10009251766 | | 2021-07-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 14547 | click or scan EU-EC-10009251716 | | 2021-07-03 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14548 | click or scan EU-EC-10009251704 | | 2021-07-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14549 | click or scan EU-EC-10009251040 | | 2021-07-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death of pet (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14550 | click or scan EU-EC-10009250973 | | 2021-07-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14551 | click or scan EU-EC-10009250788 | | 2021-07-03 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14552 | click or scan EU-EC-10009250239 | | 2021-07-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Recovered/Resolved - **Results in Death**), Neck pain (n/a - Unknown - **Results in Death**), Paraesthesia (n/a - Not Recovered/Not Resolved - **Results in Death**), Peripheral swelling (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Subclavian vein thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14553 | click or scan EU-EC-10009249557 | | 2021-07-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Gastritis (n/a - Fatal - **Results in Death**), Intestinal infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14554 | click or scan EU-EC-10009249000 | | 2021-07-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 14555 | click or scan EU-EC-10009248998 | | 2021-07-03 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14556 | click or scan EU-EC-10009248979 | | 2021-07-03 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14557 | click or scan EU-EC-10009246811 | | 2021-07-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14558 | click or scan EU-EC-10009246767 | | 2021-07-03 | Healthcare Professional | EEA | 18-64 Years | Female | Ruptured cerebral aneurysm (6d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 14559 | click or scan EU-EC-10009246728 | | 2021-07-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (38d - Fatal - **Results in Death**), Fibrin D dimer increased (38d - Fatal - **Results in Death**), Hyperkalaemia (38d - Fatal - **Results in Death**), Myoglobin blood increased (38d - Fatal - **Results in Death**), Rhabdomyolysis (38d - Fatal - **Results in Death**), Transaminases increased (38d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .4mL - Intramuscular]) |
| 14560 | click or scan EU-EC-10009248386 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14561 | click or scan EU-EC-10009248356 | | 2021-07-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14562 | click or scan EU-EC-10009248037 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14563 | click or scan EU-EC-10009247945 |  | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerotic gangrene (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood calcium decreased (n/a - Unknown - ), Blood chloride increased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood magnesium decreased (n/a - Unknown - ), Blood phosphorus increased (n/a - Unknown - ), Blood potassium increased (n/a - Unknown - ), Blood sodium decreased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), Carbon dioxide decreased (n/a - Unknown - ), Coagulopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Glomerular filtration rate decreased (n/a - Unknown - ), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Neutrophil count increased (n/a - Unknown - ), Peripheral arterial occlusive disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Unknown - ), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14564 | click or scan EU-EC-10009247910 |  | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14565 | click or scan EU-EC-10009247702 |  | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Ischaemic stroke (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - .3mL - Intramuscular]) |
| 14566 | click or scan EU-EC-10009247674 |  | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Large intestine perforation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Perforation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14567 | click or scan EU-EC-10009247643 |  | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14568 | click or scan EU-EC-10009247488 |  | 2021-07-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (5d - Fatal - **Results in Death**), Intracardiac thrombus (0d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14569 | click or scan EU-EC-10009247238 |  | 2021-07-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 14570 | click or scan EU-EC-10009247234 |  | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Female | Status epilepticus (47d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 14571 | click or scan EU-EC-10009247205 |  | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14572 | click or scan EU-EC-10009247200 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14573 | click or scan EU-EC-10009247070 | | 2021-07-02 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Gingival discolouration (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Rash (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14574 | click or scan EU-EC-10009246609 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14575 | click or scan EU-EC-10009246409 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14576 | click or scan EU-EC-10009246370 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14577 | click or scan EU-EC-10009246165 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oedema peripheral (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pruritus (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14578 | click or scan EU-EC-10009246104 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Iron deficiency anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Supraventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14579 | click or scan EU-EC-10009245667 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 14580 | click or scan EU-EC-10009245373 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14581 | click or scan EU-EC-10009245298 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14582 | click or scan EU-EC-10009244660 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14583 | click or scan EU-EC-10009244655 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14584 | click or scan EU-EC-10009244513 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14585 | click or scan EU-EC-10009244511 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14586 | click or scan EU-EC-10009244497 | | 2021-07-02 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14587 | click or scan EU-EC-10009244247 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14588 | click or scan EU-EC-10009243836 | | 2021-07-02 | Healthcare Professional | EEA | 18-64 Years | Female | Chest pain (0d - Recovered/Resolved - ), Fatigue (3d - Recovered/Resolved - ), Injection site pain (3d - Recovered/Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14589 | click or scan EU-EC-10009243820 | | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Leukopenia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [CISPLATIN] (S - Ovarian cancer - Not applicable - [n/a - n/a - n/a]) |
| 14590 | click or scan EU-EC-10009243527 | | 2021-07-02 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14591 | click or scan EU-EC-10009243205 | | 2021-07-02 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14592 | click or scan EU-EC-10009243100 | | 2021-07-02 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 14593 | click or scan EU-EC-10009243080 | | 2021-07-02 | Healthcare Professional | EEA | 18-64 Years | Female | Meningorrhagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 14594 | click or scan EU-EC-10009243070 | | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 14595 | click or scan EU-EC-10009242685 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14596 | click or scan EU-EC-10009242595 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (3d - Fatal - **Results in Death**), Snoring (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14597 | click or scan EU-EC-10009242559 | | 2021-07-02 | Non Healthcare Professional | EEA | More than 85 Years | Female | Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Thrombosis mesenteric vessel (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 14598 | click or scan EU-EC-10009242224 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14599 | click or scan EU-EC-10009242198 | | 2021-07-02 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Blood iron decreased (10d - Unknown - ), Chills (20d - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (10d - Unknown - ), Kidney infection (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (10d - Recovered/Resolved - ), Pneumonia (10d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14600 | click or scan EU-EC-10009242083 | | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (35min - Fatal - **Results in Death**), Dyspnoea (35min - Not Recovered/Not Resolved - Life Threatening), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (35min - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14601** | click or scan EU-EC-10009241943 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venous thrombosis limb (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14602** | click or scan EU-EC-10009241930 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (3d - Fatal - **Results in Death**), Asthenia (3d - Fatal - **Results in Death**), Chills (2d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14603** | click or scan EU-EC-10009241891 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **14604** | click or scan EU-EC-10009241825 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atelectasis (n/a - Fatal - **Results in Death**), Atrial enlargement (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gallbladder disorder (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lung consolidation (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neurological decompensation (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal cyst (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular enlargement (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14605** | click or scan EU-EC-10009241649 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Left ventricular dysfunction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14606** | click or scan EU-EC-10009241357 | | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14607** | click or scan EU-EC-10009241352 | | 2021-07-02 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dementia (n/a - Fatal - **Results in Death**), Gastrointestinal somatic symptom disorder (n/a - Fatal - **Results in Death**), Mental fatigue (n/a - Fatal - **Results in Death**), Urinary incontinence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14608** | click or scan EU-EC-10009240586 | | 2021-07-02 | Non Healthcare Professional | EEA | 18-64 Years | Female | Carbohydrate antigen 19-9 increased (n/a - Not Recovered/Not Resolved - Life Threatening), Carcinoembryonic antigen increased (n/a - Not Recovered/Not Resolved - Life Threatening), Pancreatic carcinoma (n/a - Fatal - **Results in Death**), Platelet count increased (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14609** | click or scan EU-EC-10009240278 | | 2021-07-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Feeling abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal replacement therapy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Road traffic accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14610 | click or scan EU-EC-10009239916 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14611 | click or scan EU-EC-10009239694 | | 2021-07-02 | Healthcare Professional | EEA | More than 85 Years | Female | Petechiae (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), ELIQUIS [APIXABAN] (S - Cerebrovascular accident prophylaxis - Not applicable - [n/a - 5mg - Oral]) |
| 14612 | click or scan EU-EC-10009239570 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14613 | click or scan EU-EC-10009239525 | | 2021-07-02 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14614 | click or scan EU-EC-10009239154 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14615 | click or scan EU-EC-10009238856 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angiogram pulmonary abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blood glucose increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Computerised tomogram abdomen normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Mental status changes (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Platelet count normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Troponin normal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 14616 | click or scan EU-EC-10009238834 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (7d - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (7d - Fatal - **Results in Death**), Pericardial effusion (7d - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (7d - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14617 | click or scan EU-EC-10009238431 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (32d - Fatal - **Results in Death**), Chest discomfort (32d - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (32d - Fatal - **Results in Death**), Myocardial infarction (32d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (32d - Fatal - **Results in Death**), Renal failure (32d - Fatal - **Results in Death**, Other Medically Important Condition), Walking aid user (32d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14618 | click or scan EU-EC-10009238336 | | 2021-07-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14619 | click or scan EU-EC-10009238231 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Gait disturbance (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Inflammation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Muscle atrophy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Muscular weakness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Tremor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Walking aid user (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14620 | click or scan EU-EC-10009238021 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Chronic left ventricular failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Diastolic dysfunction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypovolaemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal tubular necrosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep apnoea syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14621 | click or scan EU-EC-10009237596 | | 2021-07-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14622 | click or scan EU-EC-10009237474 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14623 | click or scan EU-EC-10009237265 | | 2021-07-02 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14624 | click or scan EU-EC-10009237232 | | 2021-07-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14625 | click or scan EU-EC-10009237152 | | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Recovered/Resolved - ), Headache (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), FINGOLIMOD 0.5MG CAPSULE (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14626 | click or scan EU-EC-10009237054 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14627 | click or scan EU-EC-10009237001 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bedridden (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blindness (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (4mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (16mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14628 | click or scan EU-EC-10009236941 | | 2021-07-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Cardiovascular disorder (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14629 | click or scan EU-EC-10009236741 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14630 | click or scan EU-EC-10009236596 | | 2021-07-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injection site pain (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14631 | click or scan EU-EC-10009236476 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14632 | click or scan EU-EC-10009236119 | | 2021-07-02 | Non Healthcare Professional | EEA | Not Specified | Female | Abdominal pain (n/a - Unknown - ), Arthralgia (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Enteritis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Gastritis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infected skin ulcer (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Petechiae (n/a - Unknown - ), Skin ulcer (n/a - Unknown - ), Vascular pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14633 | click or scan EU-EC-10009236002 | | 2021-07-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14634 | click or scan EU-EC-10009236001 | | 2021-07-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Diarrhoea (5130min - Recovered/Resolved - ), Vomiting (5130min - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14635 | click or scan EU-EC-10009235886 | | 2021-07-02 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14636 | click or scan EU-EC-10009234975 | | 2021-07-02 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14637 | click or scan EU-EC-10009234958 | | 2021-07-02 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (15d - Fatal - **Results in Death**), SARS-CoV-2 test positive (15d - Fatal - **Results in Death**), Vaccination failure (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14638 | click or scan EU-EC-10009233876 | | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14639 | click or scan EU-EC-10009233833 | | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14640 | click or scan EU-EC-10009233174 | | 2021-07-01 | Healthcare Professional | EEA | 18-64 Years | Male | Aspiration (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Beta haemolytic streptococcal infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Hypertensive crisis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14641 | click or scan EU-EC-10009233166 |  | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (11d - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14642 | click or scan EU-EC-10009233162 |  | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14643 | click or scan EU-EC-10009233159 |  | 2021-07-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14644 | click or scan EU-EC-10009232833 |  | 2021-07-01 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14645 | click or scan EU-EC-10009232664 |  | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14646 | click or scan EU-EC-10009232350 |  | 2021-07-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14647 | click or scan EU-EC-10009232104 |  | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Surgery (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14648 | click or scan EU-EC-10009231902 |  | 2021-07-01 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected counterfeit product (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14649 | click or scan EU-EC-10009231843 |  | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14650 | click or scan EU-EC-10009231508 |  | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14651** | click or scan EU-EC-10009231360 |  | 2021-07-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Joint range of motion decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Neck pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14652** | click or scan EU-EC-10009231089 |  | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Blood glucose increased (n/a - Fatal - **Results in Death**), Blood pressure increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14653** | click or scan EU-EC-10009230783 |  | 2021-07-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Subdural haematoma (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14654** | click or scan EU-EC-10009230676 |  | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14655** | click or scan EU-EC-10009230321 |  | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug interaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14656** | click or scan EU-EC-10009230126 |  | 2021-07-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14657** | click or scan EU-EC-10009230012 |  | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure congestive (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **14658** | click or scan EU-EC-10009229959 |  | 2021-07-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14659** | click or scan EU-EC-10009229913 |  | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14660** | click or scan EU-EC-10009229588 | | 2021-07-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (11d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (11d - Fatal - **Results in Death**), Confusional state (11d - Fatal - **Results in Death**), Cystitis (11d - Fatal - **Results in Death**), Fatigue (11d - Fatal - **Results in Death**), Hypertension (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (11d - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (11d - Fatal - **Results in Death**), Metabolic encephalopathy (11d - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (11d - Fatal - **Results in Death**), Urosepsis (11d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14661** | click or scan EU-EC-10009229514 | | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14662** | click or scan EU-EC-10009229271 | | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (3d - Fatal - **Results in Death**), Feeding disorder (3d - Fatal - **Results in Death**), Headache (3d - Fatal - **Results in Death**), Nausea (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **14663** | click or scan EU-EC-10009229219 | | 2021-07-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Hepatic failure (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14664** | click or scan EU-EC-10009229201 | | 2021-07-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14665** | click or scan EU-EC-10009229163 | | 2021-07-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Facial paralysis (4d - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14666** | click or scan EU-EC-10009228250 | | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular]) |
| **14667** | click or scan EU-EC-10009228247 | | 2021-07-01 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **14668** | click or scan EU-EC-10009228209 | | 2021-07-01 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14669** | click or scan EU-EC-10009228154 | | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Balance disorder (n/a - Fatal - **Results in Death**), Diabetes mellitus inadequate control (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Nystagmus (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14670 | click or scan EU-EC-10009228116 | | 2021-07-01 | Healthcare Professional | EEA | More than 85 Years | Female | Intracranial haematoma (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 14671 | click or scan EU-EC-10009228045 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 14672 | click or scan EU-EC-10009227782 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (2d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14673 | click or scan EU-EC-10009227635 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14674 | click or scan EU-EC-10009227608 | | 2021-07-01 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14675 | click or scan EU-EC-10009227426 | | 2021-07-01 | Non Healthcare Professional | EEA | Not Specified | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arterial catheterisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bladder catheterisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central venous catheterisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis central (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Parenteral nutrition (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rales (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14676 | click or scan EU-EC-10009227386 |  | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14677 | click or scan EU-EC-10009227183 |  | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14678 | click or scan EU-EC-10009226701 |  | 2021-07-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14679 | click or scan EU-EC-10009226689 |  | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14680 | click or scan EU-EC-10009226682 |  | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14681 | click or scan EU-EC-10009226416 |  | 2021-07-01 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Arrhythmia (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 14682 | click or scan EU-EC-10009226306 |  | 2021-07-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14683 | click or scan EU-EC-10009226035 |  | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14684 | click or scan EU-EC-10009225988 |  | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14685** | click or scan EU-EC-10009225339 | | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **14686** | click or scan EU-EC-10009225060 | | 2021-07-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Asthenia (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14687** | click or scan EU-EC-10009224766 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (n/a - Not Recovered/Not Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14688** | click or scan EU-EC-10009224745 | | 2021-07-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14689** | click or scan EU-EC-10009223871 | | 2021-07-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed mood (n/a - Unknown - ), Discomfort (n/a - Unknown - ), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Incoherent (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14690** | click or scan EU-EC-10009223867 | | 2021-07-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14691** | click or scan EU-EC-10009223845 | | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14692** | click or scan EU-EC-10009223500 | | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Acute respiratory failure (n/a - Unknown - Other Medically Important Condition), Cold sweat (n/a - Unknown - ), Malaise (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Nausea (n/a - Recovering/Resolving - ), Pallor (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14693** | click or scan EU-EC-10009222978 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14694** | click or scan EU-EC-10009222573 | | 2021-07-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diplopia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14695 | click or scan EU-EC-10009222269 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 14696 | click or scan EU-EC-10009222091 | | 2021-07-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haemolytic anaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14697 | click or scan EU-EC-10009222056 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diplegia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Monoplegia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14698 | click or scan EU-EC-10009221692 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epistaxis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Head discomfort (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Venous thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14699 | click or scan EU-EC-10009221616 | | 2021-07-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Blood creatinine increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure fluctuation (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Renal disorder (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14700 | click or scan EU-EC-10009221603 | | 2021-07-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14701 | click or scan EU-EC-10009221379 | | 2021-07-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14702 | click or scan EU-EC-10009221069 | | 2021-07-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14703 | click or scan EU-EC-10009221049 | | 2021-07-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14704 | click or scan EU-EC-10009220601 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14705 | click or scan EU-EC-10009220593 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (25d - Fatal - **Results in Death**), Interstitial lung disease (25d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14706** | click or scan EU-EC-10009220565 | | 2021-07-01 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **14707** | click or scan EU-EC-10009219967 | | 2021-07-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure congestive (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14708** | click or scan EU-EC-10009217710 | | 2021-07-01 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14709** | click or scan EU-EC-10009219676 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Carditis (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (85d - Fatal - **Results in Death**), Hepatic failure (85d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (85d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14710** | click or scan EU-EC-10009219601 | | 2021-06-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14711** | click or scan EU-EC-10009219071 | | 2021-06-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14712** | click or scan EU-EC-10009218957 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **14713** | click or scan EU-EC-10009218955 | | 2021-06-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14714** | click or scan EU-EC-10009218716 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14715** | click or scan EU-EC-10009218080 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea exertional (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14716 | click or scan EU-EC-10009217575 | | 2021-06-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 14717 | click or scan EU-EC-10009217523 | | 2021-06-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14718 | click or scan EU-EC-10009217140 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia necrotising (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia pseudomonal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14719 | click or scan EU-EC-10009217080 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blindness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14720 | click or scan EU-EC-10009216994 | | 2021-06-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 14721 | click or scan EU-EC-10009216886 | | 2021-06-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Stress cardiomyopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14722 | click or scan EU-EC-10009216881 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14723 | click or scan EU-EC-10009216598 | | 2021-06-30 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14724 | click or scan EU-EC-10009216410 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Hypersomnia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Thirst (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14725** | click or scan EU-EC-10009216266 |  | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14726** | click or scan EU-EC-10009214593 |  | 2021-06-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Hypersomnia (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Suspected COVID-19 (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14727** | click or scan EU-EC-10009214475 |  | 2021-06-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14728** | click or scan EU-EC-10009214370 |  | 2021-06-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14729** | click or scan EU-EC-10009213927 |  | 2021-06-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (44d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14730** | click or scan EU-EC-10009213920 |  | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14731** | click or scan EU-EC-10009213915 |  | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14732** | click or scan EU-EC-10009213909 |  | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14733** | click or scan EU-EC-10009213248 |  | 2021-06-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Haemoptysis (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - .3mL - Intramuscular]) |
| **14734** | click or scan EU-EC-10009213158 |  | 2021-06-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14735 | click or scan EU-EC-10009213153 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (1d - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 14736 | click or scan EU-EC-10009213120 | | 2021-06-30 | Healthcare Professional | EEA | More than 85 Years | Female | Choking (n/a - Fatal - **Results in Death**), Hypotension (1d - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 14737 | click or scan EU-EC-10009213081 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Acidosis (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Hyperlactacidaemia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ), Septic shock (n/a - Fatal - **Results in Death**), Vomiting (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [METFORMIN, METFORMIN HYDROCHLORIDE] (S - Type 2 diabetes mellitus - Dose not changed - [n/a - 2550mg - Oral]) |
| 14738 | click or scan EU-EC-10009213059 | | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 14739 | click or scan EU-EC-10009213039 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 14740 | click or scan EU-EC-10009212919 | | 2021-06-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Nausea (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (0d - Recovered/Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 14741 | click or scan EU-EC-10009212883 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 14742 | click or scan EU-EC-10009212680 | | 2021-06-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 14743 | click or scan EU-EC-10009212362 | | 2021-06-30 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14744 | click or scan EU-EC-10009211995 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14745 | click or scan EU-EC-10009211940 | | 2021-06-30 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Left ventricular hypertrophy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14746 | click or scan EU-EC-10009211924 | | 2021-06-30 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14747 | click or scan EU-EC-10009211824 | | 2021-06-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 14748 | click or scan EU-EC-10009211201 | | 2021-06-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14749 | click or scan EU-EC-10009211127 | | 2021-06-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bronchospasm (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Stridor (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14750 | click or scan EU-EC-10009210741 | | 2021-06-30 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 14751 | click or scan EU-EC-10009210709 | | 2021-06-30 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14752 | click or scan EU-EC-10009210278 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14753 | click or scan EU-EC-10009209995 | | 2021-06-30 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14754 | click or scan EU-EC-10009209948 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Hepatic haemorrhage (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14755 | click or scan EU-EC-10009209921 | | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral artery thrombosis (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14756 | click or scan EU-EC-10009209916 | | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14757 | click or scan EU-EC-10009209904 | | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14758 | click or scan EU-EC-10009209864 | | 2021-06-30 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**), Fall (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14759 | click or scan EU-EC-10009209853 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14760 | click or scan EU-EC-10009209832 | | 2021-06-30 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14761 | click or scan EU-EC-10009209829 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14762 | click or scan EU-EC-10009209742 | | 2021-06-30 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14763 | click or scan EU-EC-10009209733 | | 2021-06-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14764 | click or scan EU-EC-10009209696 | | 2021-06-30 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14765 | click or scan EU-EC-10009209651 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14766 | click or scan EU-EC-10009209574 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14767 | click or scan EU-EC-10009209029 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac asthma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 14768 | click or scan EU-EC-10009209004 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Nausea (n/a - Unknown - ), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14769 | click or scan EU-EC-10009208894 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14770 | click or scan EU-EC-10009208695 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrointestinal inflammation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14771 | click or scan EU-EC-10009208299 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14772 | click or scan EU-EC-10009207906 | | 2021-06-30 | Healthcare Professional | EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14773 | click or scan EU-EC-10009207693 | | 2021-06-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain herniation (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decerebrate posture (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Not Recovered/Not Resolved - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Inappropriate schedule of product administration (n/a - Unknown - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness (n/a - Unknown - ), Pupil fixed (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14774 | click or scan EU-EC-10009207630 | | 2021-06-30 | Healthcare Professional | EEA | 18-64 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Meningitis viral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Psychomotor hyperactivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 14775 | click or scan EU-EC-10009207426 | | 2021-06-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14776 | click or scan EU-EC-10009207100 | | 2021-06-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14777 | click or scan EU-EC-10009207063 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Fallopian tube neoplasm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nystagmus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Secondary cerebellar degeneration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertigo (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14778 | click or scan EU-EC-10009207060 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 14779 | click or scan EU-EC-10009207046 | | 2021-06-30 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14780 | click or scan EU-EC-10009207043 | | 2021-06-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Influenza like illness (n/a - Recovering/Resolving - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14781 | click or scan EU-EC-10009207023 | | 2021-06-30 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14782 | click or scan EU-EC-10009206997 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14783 | click or scan EU-EC-10009206966 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14784 | click or scan EU-EC-10009206134 | | 2021-06-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14785 | click or scan EU-EC-10009205268 | | 2021-06-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Disease progression (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14786 | click or scan EU-EC-10009203425 | | 2021-06-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 14787 | click or scan EU-EC-10009203376 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Male | Embolism (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 14788 | click or scan EU-EC-10009203370 | | 2021-06-30 | Healthcare Professional | EEA | 65-85 Years | Female | Thrombocytopenia (4d - Fatal - **Results in Death**), Transverse sinus thrombosis (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 14789 | click or scan EU-EC-10009204705 | | 2021-06-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14790 | click or scan EU-EC-10009204613 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (1d - Recovered/Resolved - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Depression (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14791 | click or scan EU-EC-10009204608 | | 2021-06-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Platelet count decreased (n/a - Unknown - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14792 | click or scan EU-EC-10009202358 | | 2021-06-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 14793 | click or scan EU-EC-10009197952 | | 2021-06-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Blood glucose increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14794 | click or scan EU-EC-10009196256 | | 2021-06-29 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 14795 | click or scan EU-EC-10009196178 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14796 | click or scan EU-EC-10009195965 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14797** | click or scan EU-EC-10009195886 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14798** | click or scan EU-EC-10009194706 | | 2021-06-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14799** | click or scan EU-EC-10009194086 | | 2021-06-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14800** | click or scan EU-EC-10009194076 | | 2021-06-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Foetal cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14801** | click or scan EU-EC-10009194070 | | 2021-06-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Erysipelas (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14802** | click or scan EU-EC-10009194067 | | 2021-06-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Hot flush (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14803** | click or scan EU-EC-10009193969 | | 2021-06-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14804** | click or scan EU-EC-10009193815 | | 2021-06-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14805** | click or scan EU-EC-10009193764 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14806** | click or scan EU-EC-10009193138 | | 2021-06-29 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14807 | click or scan EU-EC-10009193093 | | 2021-06-29 | Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster meningoencephalitis (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 14808 | click or scan EU-EC-10009193076 | | 2021-06-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14809 | click or scan EU-EC-10009193029 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14810 | click or scan EU-EC-10009192736 | | 2021-06-29 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Insomnia (n/a - Unknown - ), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - ), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14811 | click or scan EU-EC-10009192354 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac aneurysm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14812 | click or scan EU-EC-10009192300 | | 2021-06-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic cardiomyopathy (n/a - Not Recovered/Not Resolved - Life Threatening), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14813 | click or scan EU-EC-10009192230 | | 2021-06-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebellar haemorrhage (n/a - Fatal - **Results in Death**), Foramen magnum stenosis (n/a - Fatal - **Results in Death**), Hydrocephalus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 14814 | click or scan EU-EC-10009192208 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14815 | click or scan EU-EC-10009192130 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Illness - Not applicable - [n/a - n/a - Intramuscular]) |
| 14816 | click or scan EU-EC-10009192101 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14817** | click or scan EU-EC-10009192099 | | 2021-06-29 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **14818** | click or scan EU-EC-10009192082 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Brain compression (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cerebral circulatory failure (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Gastric haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypercoagulation (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **14819** | click or scan EU-EC-10009191967 | | 2021-06-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14820** | click or scan EU-EC-10009191742 | | 2021-06-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14821** | click or scan EU-EC-10009191737 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Embolism (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14822** | click or scan EU-EC-10009191731 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14823** | click or scan EU-EC-10009190765 | | 2021-06-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Contusion (n/a - Unknown - ), Death (5h - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Mouth haemorrhage (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14824** | click or scan EU-EC-10009190452 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14825** | click or scan EU-EC-10009190450 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Shock haemorrhagic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14826** | click or scan EU-EC-10009190444 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (10d - Fatal - **Results in Death**), Dyspnoea exertional (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14827 | click or scan EU-EC-10009190437 |  | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Male | Intracranial aneurysm (18h - Fatal - **Results in Death**), Subarachnoid haemorrhage (18h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14828 | click or scan EU-EC-10009190382 |  | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14829 | click or scan EU-EC-10009190362 |  | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14830 | click or scan EU-EC-10009190345 |  | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14831 | click or scan EU-EC-10009190328 |  | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14832 | click or scan EU-EC-10009190198 |  | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory failure (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interstitial lung disease (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14833 | click or scan EU-EC-10009190095 |  | 2021-06-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14834 | click or scan EU-EC-10009190047 |  | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14835 | click or scan EU-EC-10009189984 |  | 2021-06-29 | Healthcare Professional | EEA | More than 85 Years | Female | Hypersensitivity (n/a - Fatal - **Results in Death**), Laryngeal oedema (n/a - Fatal - **Results in Death**), Laryngospasm (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14836 | click or scan EU-EC-10009189732 |  | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary granuloma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14837** | click or scan EU-EC-10009189561 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (0d - Fatal - **Results in Death**), Fall (7d - Fatal - **Results in Death**), Herpes zoster (7d - Fatal - **Results in Death**), Pain of skin (9d - Fatal - **Results in Death**), Rash (9d - Fatal - **Results in Death**), Skin burning sensation (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **14838** | click or scan EU-EC-10009189491 | | 2021-06-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Malaise (n/a - Unknown - ), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14839** | click or scan EU-EC-10009189443 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **14840** | click or scan EU-EC-10009189179 | | 2021-06-29 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14841** | click or scan EU-EC-10009189139 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14842** | click or scan EU-EC-10009189059 | | 2021-06-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14843** | click or scan EU-EC-10009188971 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Female | Activated partial thromboplastin time prolonged (n/a - Unknown - ), Blood alkaline phosphatase increased (n/a - Unknown - ), Blood calcium decreased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), International normalised ratio increased (n/a - Unknown - ), Lymphocyte count decreased (n/a - Unknown - ), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Mean cell volume increased (n/a - Unknown - ), Mean platelet volume decreased (n/a - Unknown - ), Neoplasm progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neutrophil count increased (n/a - Unknown - ), Platelet count increased (n/a - Unknown - ), Prothrombin time prolonged (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Red cell distribution width increased (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14844** | click or scan EU-EC-10009188652 | | 2021-06-29 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **14845** | click or scan EU-EC-10009188648 | | 2021-06-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14846 | click or scan EU-EC-10009188240 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (8d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14847 | click or scan EU-EC-10009188115 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14848 | click or scan EU-EC-10009187947 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14849 | click or scan EU-EC-10009187853 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Compartment syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14850 | click or scan EU-EC-10009187334 | | 2021-06-29 | Non Healthcare Professional | EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14851 | click or scan EU-EC-10009187234 | | 2021-06-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14852 | click or scan EU-EC-10009187189 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14853 | click or scan EU-EC-10009186934 | | 2021-06-29 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (3d - Fatal - **Results in Death**), COVID-19 (3d - Fatal - **Results in Death**), COVID-19 pneumonia (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14854 | click or scan EU-EC-10009186879 | | 2021-06-29 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14855 | click or scan EU-EC-10009186862 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14856 | click or scan EU-EC-10009186751 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14857 | click or scan EU-EC-10009186725 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14858 | click or scan EU-EC-10009186696 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 14859 | click or scan EU-EC-10009186692 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Contusion (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphadenopathy mediastinal (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Melaena (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Retroperitoneal lymphadenopathy (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 14860 | click or scan EU-EC-10009186631 | | 2021-06-29 | Healthcare Professional | Non EEA | Not Specified | Male | Apnoea (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14861 | click or scan EU-EC-10009186621 | | 2021-06-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14862 | click or scan EU-EC-10009186604 | | 2021-06-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14863 | click or scan EU-EC-10009186554 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1d - Fatal - **Results in Death**), Chills (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination complication (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14864 | click or scan EU-EC-10009186529 | | 2021-06-29 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (4d - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Chest pain (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 14865 | click or scan EU-EC-10009185602 | | 2021-06-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14866 | click or scan EU-EC-10009185332 | | 2021-06-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Hypopnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14867 | click or scan EU-EC-10009185130 | | 2021-06-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Aphasia (2d - Fatal - **Results in Death**), Blood pressure decreased (2d - Fatal - **Results in Death**), Chest pain (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14868 | click or scan EU-EC-10009184344 | | 2021-06-29 | Healthcare Professional | EEA | 18-64 Years | Female | Intestinal infarction (19d - Fatal - **Results in Death**), Splenic infarction (19d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14869 | click or scan EU-EC-10009183853 | | 2021-06-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14870 | click or scan EU-EC-10009183804 | | 2021-06-28 | Healthcare Professional | EEA | More than 85 Years | Female | Aortic aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14871 | click or scan EU-EC-10009183307 | | 2021-06-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Fatal - **Results in Death**), Vein rupture (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - Intramuscular]) |
| 14872 | click or scan EU-EC-10009183304 | | 2021-06-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Gastric haemorrhage (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 14873 | click or scan EU-EC-10009183303 | | 2021-06-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 14874 | click or scan EU-EC-10009183297 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14875 | click or scan EU-EC-10009183231 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14876** | click or scan EU-EC-10009182696 | | 2021-06-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **14877** | click or scan EU-EC-10009182515 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal distension (16d - Fatal - **Results in Death**), Abdominal pain upper (16d - Fatal - **Results in Death**), Insomnia (16d - Fatal - **Results in Death**), Myalgia (16d - Fatal - **Results in Death**), Nausea (16d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14878** | click or scan EU-EC-10009182458 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14879** | click or scan EU-EC-10009182199 | | 2021-06-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Cerebral disorder (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Liver disorder (n/a - Fatal - **Results in Death**), Musculoskeletal disorder (n/a - Unknown - Disabling, Other Medically Important Condition), Myalgia (n/a - Unknown - ), Pain (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Renal disorder (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14880** | click or scan EU-EC-10009182009 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **14881** | click or scan EU-EC-10009181899 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14882** | click or scan EU-EC-10009181867 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [1d - n/a - Subcutaneous]) |
| **14883** | click or scan EU-EC-10009181494 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm repair (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14884** | click or scan EU-EC-10009181358 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14885** | click or scan EU-EC-10009181182 | | 2021-06-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardiac hypertrophy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14886** | click or scan EU-EC-10009181163 | | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bedridden (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14887** | click or scan EU-EC-10009181038 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]), [ADENOVIRUS SEROTYPE 26 VECTOR, RECOMBINANT, ENCODING SARS-COV-2 SPIKE PROTEIN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **14888** | click or scan EU-EC-10009181038 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]), [ADENOVIRUS SEROTYPE 26 VECTOR, RECOMBINANT, ENCODING SARS-COV-2 SPIKE PROTEIN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **14889** | click or scan EU-EC-10009180940 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **14890** | click or scan EU-EC-10009180874 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (1d - Fatal - **Results in Death**), Hypertension (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **14891** | click or scan EU-EC-10009180801 | | 2021-06-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac dysfunction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14892** | click or scan EU-EC-10009180609 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14893** | click or scan EU-EC-10009180588 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14894** | click or scan EU-EC-10009180351 | | 2021-06-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Immune system disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14895 | click or scan EU-EC-10009180305 | | 2021-06-28 | Healthcare Professional | EEA | More than 85 Years | Female | Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 14896 | click or scan EU-EC-10009180220 | | 2021-06-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral thrombosis (10d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14897 | click or scan EU-EC-10009180118 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (2d - Fatal - **Results in Death**), Cough (2d - Fatal - **Results in Death**), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Vaccination site pain (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14898 | click or scan EU-EC-10009179779 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14899 | click or scan EU-EC-10009179124 | | 2021-06-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14900 | click or scan EU-EC-10009178982 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14901 | click or scan EU-EC-10009178599 | | 2021-06-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 14902 | click or scan EU-EC-10009178094 | | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14903 | click or scan EU-EC-10009178031 | | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14904 | click or scan EU-EC-10009178029 | | 2021-06-28 | Non Healthcare Professional | EEA | Not Specified | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14905 | click or scan EU-EC-10009178023 |  | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14906 | click or scan EU-EC-10009178014 |  | 2021-06-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14907 | click or scan EU-EC-10009178007 |  | 2021-06-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Brain stem infarction (n/a - Fatal - **Results in Death**), Disturbance in attention (n/a - Not Recovered/Not Resolved - ), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14908 | click or scan EU-EC-10009177640 |  | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14909 | click or scan EU-EC-10009177613 |  | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - n/a]) |
| 14910 | click or scan EU-EC-10009177600 |  | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Male | Bronchopneumopathy (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14911 | click or scan EU-EC-10009177586 |  | 2021-06-28 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 14912 | click or scan EU-EC-10009177576 |  | 2021-06-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 14913 | click or scan EU-EC-10009177550 |  | 2021-06-28 | Healthcare Professional | EEA | 18-64 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 14914 | click or scan EU-EC-10009177526 |  | 2021-06-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14915 | click or scan EU-EC-10009176718 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleuritic pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 14916 | click or scan EU-EC-10009175893 | | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Haemolysis (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Lactic acidosis (n/a - Fatal - **Results in Death**), Night sweats (n/a - Fatal - **Results in Death**), Pruritus (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Splenomegaly (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 14917 | click or scan EU-EC-10009175857 | | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14918 | click or scan EU-EC-10009175791 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 14919 | click or scan EU-EC-10009175286 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14920 | click or scan EU-EC-10009175217 | | 2021-06-28 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown - ), Foetal growth restriction (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 14921 | click or scan EU-EC-10009175198 | | 2021-06-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Asthma (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14922 | click or scan EU-EC-10009175141 | | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14923 | click or scan EU-EC-10009175136 | | 2021-06-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Feeling hot (n/a - Not Recovered/Not Resolved - ), Language disorder (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14924 | click or scan EU-EC-10009175125 | | 2021-06-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14925 | click or scan EU-EC-10009175088 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (3d - Fatal - **Results in Death**), Death (3d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 14926 | click or scan EU-EC-10009174988 | | 2021-06-28 | Healthcare Professional | EEA | More than 85 Years | Male | Status epilepticus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14927 | click or scan EU-EC-10009174983 | | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14928 | click or scan EU-EC-10009174795 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 14929 | click or scan EU-EC-10009174753 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14930 | click or scan EU-EC-10009174693 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14931 | click or scan EU-EC-10009174517 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14932 | click or scan EU-EC-10009174463 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14933 | click or scan EU-EC-10009174453 | | 2021-06-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14934 | click or scan EU-EC-10009174450 | | 2021-06-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Dizziness (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hip fracture (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14935 | click or scan EU-EC-10009173924 | | 2021-06-28 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 14936 | click or scan EU-EC-10009173134 | | 2021-06-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aphasia (6d - Fatal - **Results in Death**), Food refusal (6d - Fatal - **Results in Death**), General physical health deterioration (6d - Fatal - **Results in Death**), Mobility decreased (6d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 14937 | click or scan EU-EC-10009172702 | | 2021-06-28 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 14938 | click or scan EU-EC-10009172647 | | 2021-06-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Colitis ischaemic (n/a - Fatal - **Results in Death**), Diarrhoea (5d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**), Vomiting (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 14939 | click or scan EU-EC-10009172544 | | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Candida sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 14940 | click or scan EU-EC-10009172526 | | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - .3mL - Intramuscular]) |
| 14941 | click or scan EU-EC-10009172351 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14942 | click or scan EU-EC-10009172254 | | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Eyelid ptosis (n/a - Recovered/Resolved - Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sciatica (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14943** | click or scan EU-EC-10009171880 |  | 2021-06-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (7d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14944** | click or scan EU-EC-10009171845 |  | 2021-06-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **14945** | click or scan EU-EC-10009171831 |  | 2021-06-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14946** | click or scan EU-EC-10009171798 |  | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **14947** | click or scan EU-EC-10009171635 |  | 2021-06-28 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **14948** | click or scan EU-EC-10009171460 |  | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **14949** | click or scan EU-EC-10009171393 |  | 2021-06-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **14950** | click or scan EU-EC-10009171245 |  | 2021-06-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **14951** | click or scan EU-EC-10009170388 |  | 2021-06-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14952** | click or scan EU-EC-10009169811 | | 2021-06-28 | Healthcare Professional | EEA | More than 85 Years | Male | Epistaxis (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Unknown]), ELIQUIS [APIXABAN] (S - Thrombosis prophylaxis - Unknown - [n/a - 5mg - Oral]) |
| **14953** | click or scan EU-EC-10009169770 | | 2021-06-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **14954** | click or scan EU-EC-10009169437 | | 2021-06-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Ascites (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Autoimmune hepatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Localised oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung neoplasm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary calcification (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **14955** | click or scan EU-EC-10009168902 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14956** | click or scan EU-EC-10009168867 | | 2021-06-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rhinitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **14957** | click or scan EU-EC-10009168153 | | 2021-06-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **14958** | click or scan<br>EU-EC-10009168014 | | 2021-06-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Angiogram cerebral abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haematoma (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral mass effect (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral ventricle dilatation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram head abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Posturing (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Retching (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **14959** | click or scan<br>EU-EC-10009167760 | | 2021-06-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14960** | click or scan<br>EU-EC-10009167756 | | 2021-06-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Illness (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **14961** | click or scan<br>EU-EC-10009167648 | | 2021-06-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **14962** | click or scan<br>EU-EC-10009167123 | | 2021-06-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14963** | click or scan<br>EU-EC-10009167122 | | 2021-06-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **14964** | click or scan<br>EU-EC-10009167114 | | 2021-06-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14965 | click or scan EU-EC-10009165705 | | 2021-06-26 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 14966 | click or scan EU-EC-10009164899 | | 2021-06-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 14967 | click or scan EU-EC-10009164672 | | 2021-06-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14968 | click or scan EU-EC-10009164542 | | 2021-06-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14969 | click or scan EU-EC-10009164537 | | 2021-06-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (696d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14970 | click or scan EU-EC-10009164202 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14971 | click or scan EU-EC-10009163931 | | 2021-06-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Infarction (n/a - Unknown - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**), Portal vein thrombosis (n/a - Unknown - **Results in Death**), Pulmonary embolism (15d - Fatal - **Results in Death**), Splenic thrombosis (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14972 | click or scan EU-EC-10009163907 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure fluctuation (n/a - Unknown - **Results in Death**), Cardiac disorder (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Lethargy (n/a - Not Recovered/Not Resolved - **Results in Death**), Muscular weakness (n/a - Not Recovered/Not Resolved - **Results in Death**), Oral mucosal discolouration (n/a - Unknown - **Results in Death**), Peripheral swelling (n/a - Not Recovered/Not Resolved - **Results in Death**), Platelet count decreased (n/a - Not Recovered/Not Resolved - **Results in Death**), Pneumonia (n/a - Not Recovered/Not Resolved - **Results in Death**), Renal failure (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 14973 | click or scan EU-EC-10009163893 | | 2021-06-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Embolism (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14974 | click or scan EU-EC-10009163892 | | 2021-06-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonitis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **14975** | click or scan EU-EC-10009163728 | | 2021-06-26 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **14976** | click or scan EU-EC-10009163540 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Thyroid disorder (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **14977** | click or scan EU-EC-10009163297 | | 2021-06-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abscess limb (17d - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Erythema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (18d - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (18d - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14978** | click or scan EU-EC-10009163267 | | 2021-06-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Autoimmune encephalopathy (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperosmolar state (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14979** | click or scan EU-EC-10009163213 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Unknown - **Results in Death**), Pericardial haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14980** | click or scan EU-EC-10009162919 | | 2021-06-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **14981** | click or scan EU-EC-10009162374 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (1wk - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (22d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary fibrosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Swelling (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **14982** | click or scan EU-EC-10009162212 | | 2021-06-26 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Limb injury (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **14983** | click or scan EU-EC-10009161871 | | 2021-06-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 14984 | click or scan EU-EC-10009161391 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial ischaemia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14985 | click or scan EU-EC-10009160442 | | 2021-06-26 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Coma (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14986 | click or scan EU-EC-10009160441 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Brain stem haemorrhage (1d - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Haemorrhagic infarction (n/a - Not Recovered/Not Resolved - **Results in Death**), Muscle fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14987 | click or scan EU-EC-10009160433 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dementia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Syncope (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Parenteral]) |
| 14988 | click or scan EU-EC-10009160407 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14989 | click or scan EU-EC-10009160379 | | 2021-06-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14990 | click or scan EU-EC-10009160356 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 14991 | click or scan EU-EC-10009160352 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14992 | click or scan EU-EC-10009160350 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**), Peripheral swelling (n/a - Not Recovered/Not Resolved - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 14993 | click or scan EU-EC-10009160339 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Recovered/Resolved - **Results in Death**), Malaise (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 14994 | click or scan EU-EC-10009160333 | | 2021-06-26 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (1d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 14995 | click or scan EU-EC-10009159873 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14996 | click or scan EU-EC-10009159851 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14997 | click or scan EU-EC-10009159680 | | 2021-06-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14998 | click or scan EU-EC-10009159659 | | 2021-06-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 14999 | click or scan EU-EC-10009159197 | | 2021-06-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15000 | click or scan EU-EC-10009159168 | | 2021-06-26 | Non Healthcare Professional | EEA | Not Specified | Female | Blood glucose decreased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15001 | click or scan EU-EC-10009159082 | | 2021-06-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Duodenitis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Toxicity to various agents (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15002 | click or scan EU-EC-10009158257 | | 2021-06-26 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (32d - Fatal - **Results in Death**), Acute kidney injury (32d - Fatal - **Results in Death**), Anuria (32d - Fatal - **Results in Death**), Bradycardia (32d - Fatal - **Results in Death**), Cardiac arrest (32d - Fatal - **Results in Death**), Hepatic failure (32d - Fatal - **Results in Death**), Hyperhidrosis (32d - Fatal - **Results in Death**), Hypotension (32d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15003** | click or scan EU-EC-10009158255 |  | 2021-06-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiogenic shock (2d - Fatal - **Results in Death**), Septic shock (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **15004** | click or scan EU-EC-10009155675 |  | 2021-06-26 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (25d - Fatal - **Results in Death**), Portal vein thrombosis (25d - Fatal - **Results in Death**), Vena cava thrombosis (25d - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **15005** | click or scan EU-EC-10009155669 |  | 2021-06-26 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (21d - Fatal - **Results in Death**), Food refusal (21d - Fatal - **Results in Death**), Hyperglycaemia (21d - Fatal - **Results in Death**), Pyrexia (21d - Fatal - **Results in Death**), Vomiting (21d - Fatal - **Results in Death**) | SPIKEVAX (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **15006** | click or scan EU-EC-10009157289 |  | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Lacunar infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15007** | click or scan EU-EC-10009156765 |  | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **15008** | click or scan EU-EC-10009156522 |  | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **15009** | click or scan EU-EC-10009156501 |  | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**), Facial asymmetry (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **15010** | click or scan EU-EC-10009156484 |  | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15011** | click or scan EU-EC-10009156382 |  | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15012** | click or scan EU-EC-10009156285 |  | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (19d - Fatal - **Results in Death**), Pneumothorax (n/a - Fatal - **Results in Death**), Pseudomonas infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15013 | click or scan EU-EC-10009155790 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Haemorrhagic infarction (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15014 | click or scan EU-EC-10009155269 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15015 | click or scan EU-EC-10009155200 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15016 | click or scan EU-EC-10009155106 | | 2021-06-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15017 | click or scan EU-EC-10009155076 | | 2021-06-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Monoplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15018 | click or scan EU-EC-10009154936 | | 2021-06-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pneumonia viral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15019 | click or scan EU-EC-10009154751 | | 2021-06-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15020 | click or scan EU-EC-10009154656 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Accelerated hypertension (n/a - Fatal - **Results in Death**), Left ventricular failure (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15021 | click or scan EU-EC-10009154495 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15022 | click or scan EU-EC-10009153924 | | 2021-06-25 | Non Healthcare Professional | EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15023 | click or scan EU-EC-10009153913 |  | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15024 | click or scan EU-EC-10009153908 |  | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15025 | click or scan EU-EC-10009153907 |  | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (3d - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (3d - Fatal - **Results in Death**), Epilepsy (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15026 | click or scan EU-EC-10009153904 |  | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15027 | click or scan EU-EC-10009153903 |  | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Male | Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15028 | click or scan EU-EC-10009153901 |  | 2021-06-25 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15029 | click or scan EU-EC-10009153714 |  | 2021-06-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Diarrhoea (2d - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (2d - Recovered/Resolved - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15030 | click or scan EU-EC-10009153462 |  | 2021-06-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arterial thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15031 | click or scan EU-EC-10009153428 |  | 2021-06-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bronchitis (n/a - Unknown - ), Chromaturia (n/a - Unknown - ), Dyspnoea (n/a - Recovered/Resolved - ), Lung cancer metastatic (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15032 | click or scan EU-EC-10009153385 |  | 2021-06-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15033 | click or scan EU-EC-10009153299 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysarthria (1d - Fatal - **Results in Death**), Lethargy (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15034 | click or scan EU-EC-10009153269 | | 2021-06-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15035 | click or scan EU-EC-10009153208 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15036 | click or scan EU-EC-10009153195 | | 2021-06-25 | Healthcare Professional | EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15037 | click or scan EU-EC-10009153169 | | 2021-06-25 | Non Healthcare Professional | EEA | Not Specified | Female | Illness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15038 | click or scan EU-EC-10009152953 | | 2021-06-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (22d - Fatal - **Results in Death**, Life Threatening, Disabling, Congenital Anomaly) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15039 | click or scan EU-EC-10009152947 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Hypertensive emergency (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15040 | click or scan EU-EC-10009152923 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15041 | click or scan EU-EC-10009152922 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (45min - Fatal - **Results in Death**), Dyspnoea (45min - Fatal - **Results in Death**), Oxygen saturation decreased (45min - Fatal - **Results in Death**), Resuscitation (45min - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15042 | click or scan EU-EC-10009152718 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15043** | click or scan EU-EC-10009152478 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15044** | click or scan EU-EC-10009152434 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15045** | click or scan EU-EC-10009152373 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (0d - Fatal - **Results in Death**), Cardiac failure acute (7d - Fatal - **Results in Death**), Pericarditis (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15046** | click or scan EU-EC-10009152298 | | 2021-06-25 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**), Respiratory rate decreased (n/a - Fatal - **Results in Death**), Seizure like phenomena (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15047** | click or scan EU-EC-10009152270 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**), Bundle branch block left (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15048** | click or scan EU-EC-10009151914 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15049** | click or scan EU-EC-10009151045 | | 2021-06-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **15050** | click or scan EU-EC-10009151015 | | 2021-06-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15051** | click or scan EU-EC-10009151008 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15052** | click or scan EU-EC-10009150982 | | 2021-06-25 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15053** | click or scan EU-EC-10009150903 | | 2021-06-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **15054** | click or scan EU-EC-10009150895 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **15055** | click or scan EU-EC-10009150889 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **15056** | click or scan EU-EC-10009150880 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **15057** | click or scan EU-EC-10009150879 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **15058** | click or scan EU-EC-10009150878 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **15059** | click or scan EU-EC-10009150853 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15060** | click or scan EU-EC-10009150852 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15061** | click or scan EU-EC-10009150385 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening), Injection site swelling (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening), Tachycardia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15062** | click or scan EU-EC-10009150180 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15063** | click or scan EU-EC-10009149244 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15064** | click or scan EU-EC-10009149231 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Body temperature increased (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Torsade de pointes (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15065** | click or scan EU-EC-10009148777 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **15066** | click or scan EU-EC-10009148521 | | 2021-06-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac asthma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Musculoskeletal pain (n/a - Unknown - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15067** | click or scan EU-EC-10009147931 | | 2021-06-25 | Healthcare Professional | EEA | 65-85 Years | Female | Immobile (n/a - Fatal - **Results in Death**), Myocardial strain imaging (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **15068** | click or scan EU-EC-10009147791 | | 2021-06-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15069** | click or scan EU-EC-10009147765 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (31d - Fatal - **Results in Death**), Lethargy (31d - Fatal - **Results in Death**), Migraine (31d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15070** | click or scan EU-EC-10009147739 | | 2021-06-25 | Non Healthcare Professional | EEA | Not Specified | Male | Cough (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Erythema (1d - Fatal - **Results in Death**), Haemoptysis (1d - Fatal - **Results in Death**), Localised oedema (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **15071** | click or scan EU-EC-10009147410 | | 2021-06-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **15072** | click or scan EU-EC-10009147324 | | 2021-06-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15073** | click or scan EU-EC-10009147136 | | 2021-06-25 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15074 | click or scan EU-EC-10009147044 | | 2021-06-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15075 | click or scan EU-EC-10009147016 | | 2021-06-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Heat illness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15076 | click or scan EU-EC-10009146756 | | 2021-06-25 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15077 | click or scan EU-EC-10009146624 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15078 | click or scan EU-EC-10009146613 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Erythema (n/a - Recovered/Resolved - ), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15079 | click or scan EU-EC-10009146610 | | 2021-06-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Renal disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15080 | click or scan EU-EC-10009146278 | | 2021-06-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15081 | click or scan EU-EC-10009146215 | | 2021-06-25 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15082 | click or scan EU-EC-10009145937 | | 2021-06-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15083 | click or scan EU-EC-10009145799 | | 2021-06-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15084 | click or scan EU-EC-10009145721 | | 2021-06-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15085 | click or scan EU-EC-10009144863 | | 2021-06-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15086 | click or scan EU-EC-10009144593 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - ), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac flutter (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - ), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15087 | click or scan EU-EC-10009144432 | | 2021-06-25 | Healthcare Professional | EEA | 18-64 Years | Female | Altered state of consciousness (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovered/Resolved - ), Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central nervous system lesion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (0d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Dyspnoea (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Folate deficiency (n/a - Unknown - ), Grunting (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (0d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (2d - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Hyperhidrosis (n/a - Unknown - ), Hypotension (0d - Fatal - **Results in Death**), Livedo reticularis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved - ), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Tension headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovered/Resolved - ), Vitamin B12 deficiency (n/a - Unknown - ), Vitamin D deficiency (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 15088 | click or scan EU-EC-10009144248 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Unknown - Other Medically Important Condition), Anal incontinence (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15089 | click or scan EU-EC-10009143201 | | 2021-06-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15090 | click or scan EU-EC-10009142827 | | 2021-06-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15091 | click or scan EU-EC-10009142541 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15092** | click or scan EU-EC-10009142526 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological symptom (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15093** | click or scan EU-EC-10009142379 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15094** | click or scan EU-EC-10009142273 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15095** | click or scan EU-EC-10009142257 | | 2021-06-24 | Healthcare Professional | Non EEA | Not Specified | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15096** | click or scan EU-EC-10009142230 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Adrenal haemorrhage (n/a - Fatal - **Results in Death**), Aortic thrombosis (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15097** | click or scan EU-EC-10009142055 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15098** | click or scan EU-EC-10009141722 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15099** | click or scan EU-EC-10009141698 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15100** | click or scan EU-EC-10009141555 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15101** | click or scan EU-EC-10009141536 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15102** | click or scan EU-EC-10009140567 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Atrial flutter (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Malaise (n/a - Unknown - ), Movement disorder (n/a - Unknown - ), Neoplasm progression (n/a - Unknown - ), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Urinary tract infection bacterial (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **15103** | click or scan EU-EC-10009140361 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15104** | click or scan EU-EC-10009140340 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15105** | click or scan EU-EC-10009139941 | | 2021-06-24 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [29d - .5mL - Parenteral]) |
| **15106** | click or scan EU-EC-10009139794 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - Life Threatening, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15107** | click or scan EU-EC-10009138800 | | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| **15108** | click or scan EU-EC-10009138670 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15109** | click or scan EU-EC-10009138573 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15110** | click or scan EU-EC-10009138552 | | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15111** | click or scan EU-EC-10009138439 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Skin discolouration (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15112 | click or scan EU-EC-10009138222 | | 2021-06-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15113 | click or scan EU-EC-10009138169 | | 2021-06-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Parenteral]) |
| 15114 | click or scan EU-EC-10009138155 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15115 | click or scan EU-EC-10009137858 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Meningococcal sepsis (n/a - Not Recovered/Not Resolved - ), Septic shock (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15116 | click or scan EU-EC-10009137790 | | 2021-06-24 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15117 | click or scan EU-EC-10009137712 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15118 | click or scan EU-EC-10009137701 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Dengue fever (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15119 | click or scan EU-EC-10009137346 | | 2021-06-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15120 | click or scan EU-EC-10009136986 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypertension (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15121 | click or scan EU-EC-10009136902 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15122 | click or scan EU-EC-10009136870 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hyporeflexia (n/a - Not Recovered/Not Resolved - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15123 | click or scan EU-EC-10009136821 |  | 2021-06-24 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly), Maternal exposure timing unspecified (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 15124 | click or scan EU-EC-10009136731 |  | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15125 | click or scan EU-EC-10009136725 |  | 2021-06-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lip pain (n/a - Unknown - ), Lip swelling (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15126 | click or scan EU-EC-10009136719 |  | 2021-06-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15127 | click or scan EU-EC-10009136648 |  | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15128 | click or scan EU-EC-10009136461 |  | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [CEFTRIAXONE, CEFTRIAXONE SODIUM] (S - Product used for unknown indication - Unknown - [n/a - n/a - n/a]) |
| 15129 | click or scan EU-EC-10009136412 |  | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Central nervous system lesion (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial pressure increased (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Memory impairment (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Migraine (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15130 | click or scan EU-EC-10009136298 |  | 2021-06-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Communication disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15131 | click or scan EU-EC-10009135797 |  | 2021-06-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Vaccination complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15132 | click or scan EU-EC-10009134499 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15133 | click or scan EU-EC-10009134329 | | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiovascular symptom (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15134 | click or scan EU-EC-10009133902 | | 2021-06-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15135 | click or scan EU-EC-10009133433 | | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |
| 15136 | click or scan EU-EC-10009133402 | | 2021-06-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 15137 | click or scan EU-EC-10009133270 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular]) |
| 15138 | click or scan EU-EC-10009133244 | | 2021-06-24 | Healthcare Professional | EEA | More than 85 Years | Male | Haemorrhagic stroke (35d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15139 | click or scan EU-EC-10009133108 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Male | Hypovolaemic shock (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15140 | click or scan EU-EC-10009132968 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Haematochezia (n/a - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), RIVAROXABAN 20MG TABLET (S - Product used for unknown indication - Drug withdrawn - [n/a - 20mg - n/a]) |
| 15141 | click or scan EU-EC-10009132880 | | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15142 | click or scan EU-EC-10009132807 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (1d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition), Dysuria (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Rash (1d - Recovered/Resolved - ), Rash macular (n/a - Unknown - ), Retching (1d - Recovered/Resolved - ), Vascular dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15143 | click or scan EU-EC-10009132581 | | 2021-06-24 | Non Healthcare Professional | Non EEA | Not Specified | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15144 | click or scan EU-EC-10009132553 | | 2021-06-24 | Non Healthcare Professional | EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspepsia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15145 | click or scan EU-EC-10009132552 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15146 | click or scan EU-EC-10009132551 | | 2021-06-24 | Non Healthcare Professional | EEA | Not Specified | Male | Arthralgia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypokinesia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15147 | click or scan EU-EC-10009132225 | | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Female | Neoplasm progression (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15148 | click or scan EU-EC-10009132207 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15149 | click or scan EU-EC-10009131765 | | 2021-06-24 | Healthcare Professional | EEA | More than 85 Years | Female | Left ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15150 | click or scan EU-EC-10009131734 | | 2021-06-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15151 | click or scan EU-EC-10009131654 | | 2021-06-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oral mucosal blistering (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Shock (n/a - Fatal - **Results in Death**), Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15152 | click or scan EU-EC-10009131128 | | 2021-06-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Sputum increased (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15153 | click or scan EU-EC-10009131094 | | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Not Recovered/Not Resolved - ), Haemodynamic instability (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Organising pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary hypertension (n/a - Fatal - **Results in Death**), Pulmonary infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Recovering/Resolving - ), Right ventricular dysfunction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15154 | click or scan EU-EC-10009130745 | | 2021-06-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Hypoaesthesia (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Pain in extremity (1d - Unknown - Other Medically Important Condition), Respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15155 | click or scan EU-EC-10009130495 | | 2021-06-24 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15156 | click or scan EU-EC-10009130443 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15157 | click or scan EU-EC-10009130435 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15158 | click or scan EU-EC-10009130399 | | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15159 | click or scan EU-EC-10009130344 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Pain in extremity (1d - Recovered/Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15160 | click or scan EU-EC-10009129645 | | 2021-06-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (16d - Fatal - **Results in Death**) | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15161 | click or scan EU-EC-10009129621 |  | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Male | Agitation (n/a - Unknown - **Results in Death**), Chills (n/a - Unknown - **Results in Death**), Communication disorder (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Mobility decreased (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - .5mL - Intramuscular]) |
| 15162 | click or scan EU-EC-10009129487 |  | 2021-06-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aspiration (n/a - Fatal - **Results in Death**), Generalised tonic-clonic seizure (10min - Unknown - Other Medically Important Condition), Lung disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15163 | click or scan EU-EC-10009129386 |  | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Agitation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15164 | click or scan EU-EC-10009129144 |  | 2021-06-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15165 | click or scan EU-EC-10009129081 |  | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15166 | click or scan EU-EC-10009128707 |  | 2021-06-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15167 | click or scan EU-EC-10009128476 |  | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15168 | click or scan EU-EC-10009128249 |  | 2021-06-24 | Healthcare Professional | EEA | 18-64 Years | Female | Anxiety (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (0d - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (0d - Recovered/Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (0d - Fatal - **Results in Death**, Other Medically Important Condition), Haemoptysis (0d - Fatal - **Results in Death**, Other Medically Important Condition), Urticaria (0d - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 15169 | click or scan EU-EC-10009128220 |  | 2021-06-24 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15170 | click or scan EU-EC-10009128219 | | 2021-06-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15171 | click or scan EU-EC-10009126704 | | 2021-06-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15172 | click or scan EU-EC-10009125827 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperkalaemia (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15173 | click or scan EU-EC-10009125751 | | 2021-06-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - ), Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Influenza like illness (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15174 | click or scan EU-EC-10009125551 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15175 | click or scan EU-EC-10009125529 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15176 | click or scan EU-EC-10009125225 | | 2021-06-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), Condition aggravated (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fall (n/a - Unknown - ), Neck pain (n/a - Unknown - ), Pain (n/a - Not Recovered/Not Resolved - ), Paresis (n/a - Unknown - ), Peripheral venous disease (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Spinal disorder (n/a - Unknown - ), Urinary retention (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15177 | click or scan EU-EC-10009124144 | | 2021-06-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), HCoV-OC43 infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Orthostatic hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral T-cell lymphoma unspecified (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory symptom (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15178 | click or scan EU-EC-10009122282 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (8d - Fatal - **Results in Death**), Rectal haemorrhage (8d - Fatal - **Results in Death**), Syncope (8d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 15179 | click or scan EU-EC-10009122267 | | 2021-06-24 | Healthcare Professional | EEA | 65-85 Years | Male | Dysphagia (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15180 | click or scan EU-EC-10009123905 | | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Incorrect dose administered (1d - Recovered/Resolved - ), Somnolence (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vision blurred (2mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15181 | click or scan EU-EC-10009123883 | | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Haematemesis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15182 | click or scan EU-EC-10009123754 | | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 15183 | click or scan EU-EC-10009123618 | | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15184 | click or scan EU-EC-10009123370 | | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15185 | click or scan EU-EC-10009123203 | | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute left ventricular failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperthyroidism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15186 | click or scan EU-EC-10009123198 | | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15187 | click or scan EU-EC-10009123078 | | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15188 | click or scan EU-EC-10009122842 |  | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Acute kidney injury (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15189 | click or scan EU-EC-10009122620 |  | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15190 | click or scan EU-EC-10009121757 |  | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15191 | click or scan EU-EC-10009121457 |  | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac murmur (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Weight decreased (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 15192 | click or scan EU-EC-10009121341 |  | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15193 | click or scan EU-EC-10009121255 |  | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (5d - Fatal - **Results in Death**), Pain (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15194 | click or scan EU-EC-10009121150 |  | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral thrombosis (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15195 | click or scan EU-EC-10009120761 |  | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Visceral venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 15196 | click or scan EU-EC-10009120747 |  | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (99d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Haematuria (99d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15197 | click or scan EU-EC-10009120699 |  | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Hypophagia (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15198 | click or scan EU-EC-10009120429 | | 2021-06-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**), Fatigue (3d - Fatal - **Results in Death**), Malaise (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15199 | click or scan EU-EC-10009120428 | | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**), Vascular graft thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15200 | click or scan EU-EC-10009120425 | | 2021-06-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15201 | click or scan EU-EC-10009120325 | | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15202 | click or scan EU-EC-10009120279 | | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15203 | click or scan EU-EC-10009119429 | | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15204 | click or scan EU-EC-10009119362 | | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Male | Antiphospholipid syndrome (n/a - Fatal - **Results in Death**), Asthenia (n/a - Not Recovered/Not Resolved - ), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15205 | click or scan EU-EC-10009119361 | | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Chest pain (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15206 | click or scan EU-EC-10009119347 | | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15207 | click or scan EU-EC-10009119247 | | 2021-06-23 | Healthcare Professional | EEA | More than 85 Years | Male | Subdural haematoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), ELIQUIS [APIXABAN] (S - Atrial fibrillation - Drug withdrawn - [n/a - 5mg - Oral]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15208 | click or scan EU-EC-10009119237 |  | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 15209 | click or scan EU-EC-10009119229 |  | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 15210 | click or scan EU-EC-10009119147 |  | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 15211 | click or scan EU-EC-10009119056 |  | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Male | Aphasia (n/a - Unknown - ), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Heparin-induced thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Immune thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Vertigo (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15212 | click or scan EU-EC-10009118995 |  | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 15213 | click or scan EU-EC-10009118887 |  | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15214 | click or scan EU-EC-10009118779 |  | 2021-06-23 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal heart rate abnormal (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15215 | click or scan EU-EC-10009118623 |  | 2021-06-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15216 | click or scan EU-EC-10009117975 |  | 2021-06-23 | Healthcare Professional | Non EEA | Not Specified | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15217 | click or scan EU-EC-10009117850 |  | 2021-06-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15218 | click or scan EU-EC-10009117846 |  | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15219 | click or scan EU-EC-10009117582 | | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Female | Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15220 | click or scan EU-EC-10009117417 | | 2021-06-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15221 | click or scan EU-EC-10009116360 | | 2021-06-23 | Healthcare Professional | Non EEA | Not Specified | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15222 | click or scan EU-EC-10009115071 | | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15223 | click or scan EU-EC-10009114671 | | 2021-06-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15224 | click or scan EU-EC-10009114550 | | 2021-06-23 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15225 | click or scan EU-EC-10009114456 | | 2021-06-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Subcutaneous]) |
| 15226 | click or scan EU-EC-10009113970 | | 2021-06-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15227 | click or scan EU-EC-10009113937 | | 2021-06-23 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (91d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15228 | click or scan EU-EC-10009113856 | | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15229** | click or scan EU-EC-10009113425 | | 2021-06-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Fatal - **Results in Death**), Headache (14d - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (14d - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15230** | click or scan EU-EC-10009113306 | | 2021-06-23 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15231** | click or scan EU-EC-10009113230 | | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (1h - Fatal - **Results in Death**), Chills (4d - Fatal - **Results in Death**), Fall (4d - Fatal - **Results in Death**), Fatigue (4d - Fatal - **Results in Death**), Malaise (4d - Fatal - **Results in Death**), Myalgia (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**), Sudden death (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15232** | click or scan EU-EC-10009112537 | | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Vaccination site pain (6d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15233** | click or scan EU-EC-10009112466 | | 2021-06-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15234** | click or scan EU-EC-10009112365 | | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15235** | click or scan EU-EC-10009112292 | | 2021-06-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Weight increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15236** | click or scan EU-EC-10009112273 | | 2021-06-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abdominal pain upper (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abdominal sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood uric acid increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal necrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic function abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Labile blood pressure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Perforation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15237 | click or scan EU-EC-10009111988 | | 2021-06-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15238 | click or scan EU-EC-10009111919 | | 2021-06-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15239 | click or scan EU-EC-10009111397 | | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15240 | click or scan EU-EC-10009111375 | | 2021-06-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastritis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15241 | click or scan EU-EC-10009111368 | | 2021-06-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15242 | click or scan EU-EC-10009109602 | | 2021-06-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15243 | click or scan EU-EC-10009109323 | | 2021-06-22 | Healthcare Professional | Non EEA | Not Specified | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15244 | click or scan EU-EC-10009108927 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Female | Carotid artery occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15245 | click or scan EU-EC-10009108191 | | 2021-06-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Bedridden (n/a - Unknown - ), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Dehydration (n/a - Unknown - ), Delirium (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Haematochezia (n/a - Unknown - Other Medically Important Condition), Protein deficiency (n/a - Unknown - ), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15246 | click or scan EU-EC-10009107567 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Acute kidney injury (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15247 | click or scan EU-EC-10009107403 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - ), Arthralgia (n/a - Unknown - ), Body temperature decreased (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Poor quality sleep (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15248 | click or scan EU-EC-10009107011 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15249 | click or scan EU-EC-10009106920 | | 2021-06-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - ), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15250 | click or scan EU-EC-10009106867 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15251 | click or scan EU-EC-10009106779 | | 2021-06-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Illness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15252 | click or scan EU-EC-10009105186 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15253 | click or scan EU-EC-10009105153 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15254 | click or scan EU-EC-10009104599 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 15255 | click or scan EU-EC-10009104570 | | 2021-06-22 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 15256 | click or scan EU-EC-10009104567 | | 2021-06-22 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 15257 | click or scan EU-EC-10009104452 | | 2021-06-22 | Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15258 | click or scan EU-EC-10009104443 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15259 | click or scan EU-EC-10009104441 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [50d - 2 {DF} - Intramuscular]) |
| 15260 | click or scan EU-EC-10009104329 | | 2021-06-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15261 | click or scan EU-EC-10009103759 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15262 | click or scan EU-EC-10009103740 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Neoplasm progression (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15263 | click or scan EU-EC-10009103730 | | 2021-06-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Rectal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15264 | click or scan EU-EC-10009103725 | | 2021-06-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15265 | click or scan EU-EC-10009103572 | | 2021-06-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15266 | click or scan EU-EC-10009103438 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15267 | click or scan EU-EC-10009102229 | | 2021-06-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Back pain (58d - Fatal - **Results in Death**), Decreased appetite (58d - Fatal - **Results in Death**), Fatigue (58d - Fatal - **Results in Death**), Insomnia (58d - Fatal - **Results in Death**), Liver tenderness (58d - Fatal - **Results in Death**), Nausea (58d - Fatal - **Results in Death**), Portal vein thrombosis (58d - Fatal - **Results in Death**), Pyrexia (58d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15268 | click or scan EU-EC-10009100759 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15269 | click or scan EU-EC-10009100757 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Myocardial infarction (17d - Fatal - **Results in Death**), Pneumonia aspiration (17d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15270 | click or scan EU-EC-10009100691 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15271 | click or scan EU-EC-10009100550 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15272 | click or scan EU-EC-10009100453 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15273 | click or scan EU-EC-10009100428 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15274 | click or scan EU-EC-10009100305 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15275 | click or scan EU-EC-10009100130 | | 2021-06-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15276 | click or scan EU-EC-10009100044 | | 2021-06-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intra-abdominal fluid collection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15277 | click or scan EU-EC-10009099662 | | 2021-06-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15278** | click or scan EU-EC-10009099658 | | 2021-06-22 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **15279** | click or scan EU-EC-10009099594 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rash (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urosepsis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Wrong product administered (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15280** | click or scan EU-EC-10009099594 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rash (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urosepsis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Wrong product administered (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15281** | click or scan EU-EC-10009099365 | | 2021-06-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **15282** | click or scan EU-EC-10009098992 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **15283** | click or scan EU-EC-10009098987 | | 2021-06-22 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **15284** | click or scan EU-EC-10009098913 | | 2021-06-22 | Healthcare Professional | EEA | More than 85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15285** | click or scan EU-EC-10009098811 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **15286** | click or scan EU-EC-10009098774 | | 2021-06-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15287** | click or scan EU-EC-10009098555 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15288** | click or scan EU-EC-10009098314 | | 2021-06-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15289** | click or scan EU-EC-10009098199 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **15290** | click or scan EU-EC-10009098198 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Hallucination (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15291** | click or scan EU-EC-10009098180 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diabetes mellitus (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15292** | click or scan EU-EC-10009098165 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **15293** | click or scan EU-EC-10009097759 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15294** | click or scan EU-EC-10009097673 | | 2021-06-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bradycardia (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Gaze palsy (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **15295** | click or scan EU-EC-10009097662 | | 2021-06-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15296** | click or scan EU-EC-10009097262 | | 2021-06-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15297** | click or scan EU-EC-10009097257 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15298 | click or scan EU-EC-10009096802 | | 2021-06-22 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15299 | click or scan EU-EC-10009096780 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15300 | click or scan EU-EC-10009096767 | | 2021-06-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15301 | click or scan EU-EC-10009096439 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac tamponade (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15302 | click or scan EU-EC-10009096409 | | 2021-06-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Stridor (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Use of accessory respiratory muscles (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15303 | click or scan EU-EC-10009096257 | | 2021-06-22 | Non Healthcare Professional | EEA | Not Specified | Male | Haemorrhage (n/a - Fatal - **Results in Death**), Vertigo (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15304 | click or scan EU-EC-10009096256 | | 2021-06-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypertrophic cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15305 | click or scan EU-EC-10009096213 | | 2021-06-22 | Non Healthcare Professional | EEA | Not Specified | Male | Coagulopathy (n/a - Unknown - ), Contusion (n/a - Unknown - ), Feeling abnormal (3wk - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**), Respiratory tract haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15306 | click or scan EU-EC-10009096149 | | 2021-06-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15307 | click or scan EU-EC-10009095528 | | 2021-06-21 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Subarachnoid haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15308** | click or scan EU-EC-10009095174 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15309** | click or scan EU-EC-10009094862 | | 2021-06-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Unknown - ), Infection (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **15310** | click or scan EU-EC-10009094796 | | 2021-06-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15311** | click or scan EU-EC-10009094793 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Gastroenteritis (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15312** | click or scan EU-EC-10009094712 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Feeling abnormal (2d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15313** | click or scan EU-EC-10009094656 | | 2021-06-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - ), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **15314** | click or scan EU-EC-10009094654 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15315** | click or scan EU-EC-10009094578 | | 2021-06-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **15316** | click or scan EU-EC-10009094548 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15317** | click or scan EU-EC-10009094521 | | 2021-06-21 | Healthcare Professional | EEA | 18-64 Years | Male | Hepatic vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Raynaud's phenomenon (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15318 | click or scan EU-EC-10009093966 | | 2021-06-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysuria (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal pain (n/a - Not Recovered/Not Resolved - ), Sleep disorder (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15319 | click or scan EU-EC-10009093842 | | 2021-06-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15320 | click or scan EU-EC-10009093729 | | 2021-06-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15321 | click or scan EU-EC-10009093676 | | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Condition aggravated (1d - Fatal - **Results in Death**), Hypertension (1d - Fatal - **Results in Death**), Oedema peripheral (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15322 | click or scan EU-EC-10009093594 | | 2021-06-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15323 | click or scan EU-EC-10009093539 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Inflammation (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15324 | click or scan EU-EC-10009093382 | | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (5d - Fatal - **Results in Death**), Dyspnoea (5d - Fatal - **Results in Death**), Fatigue (5d - Fatal - **Results in Death**), Pulmonary embolism (5d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15325 | click or scan EU-EC-10009093188 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Cardiac fibrillation - n/a - [n/a - n/a - n/a]) |
| 15326 | click or scan EU-EC-10009092941 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ejection fraction decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Follicular lymphoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15327 | click or scan EU-EC-10009092681 | | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral ventricular rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thalamus haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15328 | click or scan EU-EC-10009092339 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15329 | click or scan EU-EC-10009092261 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subdural haemorrhage (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15330 | click or scan EU-EC-10009091348 | | 2021-06-21 | Healthcare Professional | EEA | 18-64 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15331 | click or scan EU-EC-10009091134 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral artery embolism (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15332 | click or scan EU-EC-10009090593 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15333 | click or scan EU-EC-10009090282 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracardiac thrombus (13d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (13d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombolysis (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15334 | click or scan EU-EC-10009090072 | | 2021-06-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 15335 | click or scan EU-EC-10009090064 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15336 | click or scan EU-EC-10009089965 | | 2021-06-21 | Healthcare Professional | EEA | More than 85 Years | Male | Coma (5d - Fatal - **Results in Death**), General physical health deterioration (5d - Fatal - **Results in Death**), Hypoxia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 15337 | click or scan EU-EC-10009089912 | | 2021-06-21 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Platelet count decreased (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15338 | click or scan EU-EC-10009089863 |  | 2021-06-21 | Healthcare Professional | EEA | 18-64 Years | Male | Breast pain (3d - Fatal - **Results in Death**), Malaise (3d - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15339 | click or scan EU-EC-10009089851 |  | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15340 | click or scan EU-EC-10009089830 |  | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15341 | click or scan EU-EC-10009089817 |  | 2021-06-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15342 | click or scan EU-EC-10009089144 |  | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15343 | click or scan EU-EC-10009088468 |  | 2021-06-21 | Healthcare Professional | EEA | More than 85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15344 | click or scan EU-EC-10009088467 |  | 2021-06-21 | Healthcare Professional | EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15345 | click or scan EU-EC-10009088461 |  | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15346 | click or scan EU-EC-10009088334 |  | 2021-06-21 | Healthcare Professional | EEA | More than 85 Years | Female | Hypoalbuminaemia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15347 | click or scan EU-EC-10009088103 |  | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoosmolar state (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15348 | click or scan EU-EC-10009088015 |  | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (2d - Fatal - **Results in Death**), Cardiovascular disorder (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15349** | click or scan EU-EC-10009088008 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15350** | click or scan EU-EC-10009087650 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15351** | click or scan EU-EC-10009087633 | | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15352** | click or scan EU-EC-10009087599 | | 2021-06-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15353** | click or scan EU-EC-10009087442 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15354** | click or scan EU-EC-10009087440 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **15355** | click or scan EU-EC-10009087119 | | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15356** | click or scan EU-EC-10009087083 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15357** | click or scan EU-EC-10009087049 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15358** | click or scan EU-EC-10009086989 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15359 | click or scan EU-EC-10009086915 |  | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Obturator hernia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15360 | click or scan EU-EC-10009086820 |  | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15361 | click or scan EU-EC-10009086370 |  | 2021-06-21 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15362 | click or scan EU-EC-10009086344 |  | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15363 | click or scan EU-EC-10009086254 |  | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15364 | click or scan EU-EC-10009086173 |  | 2021-06-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bone pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cells in urine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 15365 | click or scan EU-EC-10009085979 |  | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15366 | click or scan EU-EC-10009085898 |  | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15367 | click or scan EU-EC-10009085847 |  | 2021-06-21 | Healthcare Professional | EEA | 18-64 Years | Male | Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15368 | click or scan EU-EC-10009085668 |  | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15369 | click or scan EU-EC-10009085661 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 15370 | click or scan EU-EC-10009085642 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15371 | click or scan EU-EC-10009085518 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15372 | click or scan EU-EC-10009085263 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15373 | click or scan EU-EC-10009085261 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15374 | click or scan EU-EC-10009085238 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15375 | click or scan EU-EC-10009085237 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15376 | click or scan EU-EC-10009085232 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15377 | click or scan EU-EC-10009085225 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15378 | click or scan EU-EC-10009085215 | | 2021-06-21 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 15379 | click or scan EU-EC-10009084999 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15380** | click or scan EU-EC-10009084998 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15381** | click or scan EU-EC-10009084965 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15382** | click or scan EU-EC-10009084952 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15383** | click or scan EU-EC-10009084927 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15384** | click or scan EU-EC-10009084921 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15385** | click or scan EU-EC-10009084797 | | 2021-06-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Back pain (76d - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (76d - Unknown - Other Medically Important Condition), Sciatica (76d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15386** | click or scan EU-EC-10009084764 | | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15387** | click or scan EU-EC-10009084763 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foaming at mouth (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15388** | click or scan EU-EC-10009084761 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (4d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (4d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (4d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15389** | click or scan EU-EC-10009084530 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Heart rate irregular (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15390 | click or scan EU-EC-10009084187 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15391 | click or scan EU-EC-10009084158 | | 2021-06-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Recovering/Resolving - ), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Recovering/Resolving - ), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Mobility decreased (n/a - Recovering/Resolving - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15392 | click or scan EU-EC-10009083643 | | 2021-06-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest discomfort (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15393 | click or scan EU-EC-10009083536 | | 2021-06-21 | Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (8d - Fatal - **Results in Death**), Cerebral haemorrhage (8d - Fatal - **Results in Death**), Chest pain (8d - Fatal - **Results in Death**), Headache (8d - Fatal - **Results in Death**), Hemiparesis (8d - Fatal - **Results in Death**), Pain in extremity (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15394 | click or scan EU-EC-10009083390 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15395 | click or scan EU-EC-10009083200 | | 2021-06-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hypersomnia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15396 | click or scan EU-EC-10009081811 | | 2021-06-20 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Unknown - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15397 | click or scan EU-EC-10009081421 | | 2021-06-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (57d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (57d - Fatal - **Results in Death**), Dehydration (57d - Fatal - **Results in Death**), General physical health deterioration (57d - Fatal - **Results in Death**), Illness (57d - Fatal - **Results in Death**), Immediate post-injection reaction (57d - Fatal - **Results in Death**), Malnutrition (57d - Fatal - **Results in Death**), Staphylococcal sepsis (57d - Fatal - **Results in Death**, Other Medically Important Condition), Weight decreased (57d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15398 | click or scan EU-EC-10009081418 | | 2021-06-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15399 | click or scan EU-EC-10009081227 | | 2021-06-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15400 | click or scan EU-EC-10009081223 | | 2021-06-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15401 | click or scan EU-EC-10009081105 | | 2021-06-20 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15402 | click or scan EU-EC-10009081038 | | 2021-06-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15403 | click or scan EU-EC-10009080755 | | 2021-06-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15404 | click or scan EU-EC-10009080258 | | 2021-06-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15405 | click or scan EU-EC-10009080080 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Blindness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Lung adenocarcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neck pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15406 | click or scan EU-EC-10009080070 | | 2021-06-19 | Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15407 | click or scan EU-EC-10009079937 | | 2021-06-19 | Healthcare Professional | Non EEA | Not Specified | Male | Myalgia (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15408 | click or scan EU-EC-10009079928 | | 2021-06-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Foetal exposure during pregnancy (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Transplacental]) |
| 15409 | click or scan EU-EC-10009079909 | | 2021-06-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Urosepsis (7d - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15410 | click or scan EU-EC-10009079900 | | 2021-06-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Adrenomegaly (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhagic adrenal infarction (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Lower respiratory tract infection (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Mental impairment (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Nausea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pelvic venous thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pulmonary embolism (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Respiratory failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Sepsis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombotic thrombocytopenic purpura (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vomiting projectile (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15411 | click or scan EU-EC-10009079887 | | 2021-06-19 | Healthcare Professional | Non EEA | Not Specified | Female | Rhabdomyolysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 15412 | click or scan EU-EC-10009079875 | | 2021-06-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15413 | click or scan EU-EC-10009079868 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15414 | click or scan EU-EC-10009079862 | | 2021-06-19 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15415 | click or scan EU-EC-10009079861 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15416 | click or scan EU-EC-10009079850 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chromaturia (n/a - Not Recovered/Not Resolved - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - **Results in Death**), Illness (n/a - Not Recovered/Not Resolved - **Results in Death**), Incontinence (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary hypertension (n/a - Fatal - **Results in Death**), Urinary retention (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 15417 | click or scan EU-EC-10009079842 | | 2021-06-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Recovering/Resolving - **Results in Death**), Vomiting (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15418 | click or scan EU-EC-10009079822 | | 2021-06-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 15419 | click or scan EU-EC-10009079788 | | 2021-06-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 15420 | click or scan EU-EC-10009079747 | | 2021-06-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (n/a - Unknown - **Results in Death**, Life Threatening), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening), Headache (n/a - Unknown - **Results in Death**, Life Threatening), Malaise (n/a - Unknown - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15421 | click or scan EU-EC-10009079733 | | 2021-06-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15422 | click or scan EU-EC-10009079726 | | 2021-06-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (33d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15423 | click or scan EU-EC-10009079709 | | 2021-06-19 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Productive cough (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sepsis (n/a - Not Recovered/Not Resolved - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 15424 | click or scan EU-EC-10009079633 | | 2021-06-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15425 | click or scan EU-EC-10009079585 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15426 | click or scan EU-EC-10009078226 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15427 | click or scan EU-EC-10009078157 | | 2021-06-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15428 | click or scan EU-EC-10009078142 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15429 | click or scan EU-EC-10009077660 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15430 | click or scan EU-EC-10009077658 | | 2021-06-19 | Healthcare Professional | Non EEA | Not Specified | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 15431 | click or scan EU-EC-10009077473 | | 2021-06-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15432 | click or scan EU-EC-10009077421 | | 2021-06-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15433 | click or scan EU-EC-10009077072 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Gastric haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 15434 | click or scan EU-EC-10009077038 | | 2021-06-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Chills (n/a - Unknown - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Hyperhidrosis (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15435 | click or scan EU-EC-10009076995 | | 2021-06-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acidosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (1d - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15436 | click or scan EU-EC-10009076713 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood disorder (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Rash pruritic (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 15437 | click or scan EU-EC-10009076694 | | 2021-06-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15438** | click or scan EU-EC-10009076522 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - **Results in Death**), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Immune thrombocytopenia (n/a - Unknown - **Results in Death**), Iridocyclitis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **15439** | click or scan EU-EC-10009076130 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (28d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **15440** | click or scan EU-EC-10009075458 | | 2021-06-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15441** | click or scan EU-EC-10009075202 | | 2021-06-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| **15442** | click or scan EU-EC-10009075055 | | 2021-06-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Brain injury (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15443** | click or scan EU-EC-10009074684 | | 2021-06-19 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **15444** | click or scan EU-EC-10009074648 | | 2021-06-19 | Healthcare Professional | EEA | More than 85 Years | Female | Anuria (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **15445** | click or scan EU-EC-10009074428 | | 2021-06-19 | Healthcare Professional | EEA | 65-85 Years | Male | Melaena (3d - Fatal - **Results in Death**), Pneumonitis (3d - Fatal - **Results in Death**), Septic shock (3d - Fatal - **Results in Death**), Vomiting (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **15446** | click or scan EU-EC-10009074020 | | 2021-06-19 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral ischaemia (13d - Fatal - **Results in Death**), Portal vein thrombosis (13d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - n/a]) |
| **15447** | click or scan EU-EC-10009073447 | | 2021-06-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15448** | click or scan EU-EC-10009073364 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15449** | click or scan EU-EC-10009073083 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15450** | click or scan EU-EC-10009073021 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15451** | click or scan EU-EC-10009072965 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea exertional (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15452** | click or scan EU-EC-10009072830 | | 2021-06-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vision blurred (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15453** | click or scan EU-EC-10009072783 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15454** | click or scan EU-EC-10009072698 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15455** | click or scan EU-EC-10009072660 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15456** | click or scan EU-EC-10009072557 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15457** | click or scan EU-EC-10009072435 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Road traffic accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15458** | click or scan EU-EC-10009072346 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15459 | click or scan EU-EC-10009072280 | | 2021-06-18 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal heart rate abnormal (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 15460 | click or scan EU-EC-10009072060 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15461 | click or scan EU-EC-10009072049 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15462 | click or scan EU-EC-10009072042 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15463 | click or scan EU-EC-10009071880 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (4d - Fatal - **Results in Death**, Other Medically Important Condition), Cough (4d - Fatal - **Results in Death**), Dyspnoea (4d - Fatal - **Results in Death**), Respiratory tract congestion (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15464 | click or scan EU-EC-10009071771 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chronic kidney disease (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15465 | click or scan EU-EC-10009071596 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15466 | click or scan EU-EC-10009071513 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 15467 | click or scan EU-EC-10009071445 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15468 | click or scan EU-EC-10009071378 | | 2021-06-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15469 | click or scan EU-EC-10009071365 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (117min - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (117min - Fatal - **Results in Death**), Rales (117min - Fatal - **Results in Death**), Respiratory tract congestion (117min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15470 | click or scan EU-EC-10009071192 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aneurysm (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15471 | click or scan EU-EC-10009071083 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Carotid artery thrombosis (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 15472 | click or scan EU-EC-10009070706 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15473 | click or scan EU-EC-10009070393 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening), Rhabdomyolysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 15474 | click or scan EU-EC-10009070246 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 15475 | click or scan EU-EC-10009069952 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15476 | click or scan EU-EC-10009069895 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiogenic shock (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15477 | click or scan EU-EC-10009069536 | | 2021-06-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Arthralgia (n/a - Unknown - ), Back pain (n/a - Unknown - ), Bacterial infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - ), Dengue fever (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15478 | click or scan EU-EC-10009069224 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15479 | click or scan EU-EC-10009068329 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15480** | click or scan EU-EC-10009068108 | | 2021-06-18 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15481** | click or scan EU-EC-10009068068 | | 2021-06-18 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15482** | click or scan EU-EC-10009067796 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Klebsiella sepsis (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15483** | click or scan EU-EC-10009067629 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15484** | click or scan EU-EC-10009067622 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15485** | click or scan EU-EC-10009067610 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15486** | click or scan EU-EC-10009067608 | | 2021-06-18 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15487** | click or scan EU-EC-10009067418 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15488** | click or scan EU-EC-10009067401 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15489** | click or scan EU-EC-10009067280 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15490** | click or scan EU-EC-10009067210 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |
| **15491** | click or scan EU-EC-10009067208 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15492** | click or scan EU-EC-10009067202 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |
| **15493** | click or scan EU-EC-10009067124 | | 2021-06-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **15494** | click or scan EU-EC-10009067098 | | 2021-06-18 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **15495** | click or scan EU-EC-10009067079 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **15496** | click or scan EU-EC-10009067047 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **15497** | click or scan EU-EC-10009066988 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Influenza like illness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **15498** | click or scan EU-EC-10009066972 | | 2021-06-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15499** | click or scan EU-EC-10009066139 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15500** | click or scan EU-EC-10009065813 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (0d - Fatal - **Results in Death**), Thrombocytopenia (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15501** | click or scan EU-EC-10009065540 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **15502** | click or scan EU-EC-10009065516 | | 2021-06-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15503** | click or scan EU-EC-10009065349 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15504** | click or scan EU-EC-10009065348 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15505** | click or scan EU-EC-10009065309 | | 2021-06-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **15506** | click or scan EU-EC-10009064882 | | 2021-06-18 | Healthcare Professional | EEA | 18-64 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypertensive crisis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15507** | click or scan EU-EC-10009064535 | | 2021-06-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **15508** | click or scan EU-EC-10009064120 | | 2021-06-18 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15509** | click or scan EU-EC-10009063705 | | 2021-06-18 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral artery thrombosis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15510 | click or scan EU-EC-10009062851 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 15511 | click or scan EU-EC-10009062238 | | 2021-06-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15512 | click or scan EU-EC-10009061941 | | 2021-06-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15513 | click or scan EU-EC-10009061528 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (6d - Fatal - **Results in Death**), Gait disturbance (6d - Fatal - **Results in Death**), Malaise (7d - Fatal - **Results in Death**), Myalgia (6d - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 15514 | click or scan EU-EC-10009061336 | | 2021-06-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral artery embolism (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (12d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30s - 1 {DF} - Intramuscular - More in ICSR]) |
| 15515 | click or scan EU-EC-10009061151 | | 2021-06-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15516 | click or scan EU-EC-10009060493 | | 2021-06-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Activated partial thromboplastin time prolonged (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Poor peripheral circulation (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), HUMAN NORMAL IMMUNOGLOBULIN [HUMAN NORMAL IMMUNOGLOBULIN] (S - Product used for unknown indication - Unknown - [n/a - n/a - n/a]) |
| 15517 | click or scan EU-EC-10009056886 | | 2021-06-18 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure inadequately controlled (29d - Fatal - **Results in Death**), Cognitive disorder (29d - Fatal - **Results in Death**), Pyrexia (29d - Fatal - **Results in Death**), Sopor (29d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15518 | click or scan EU-EC-10009058882 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15519** | click or scan EU-EC-10009058783 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **15520** | click or scan EU-EC-10009058609 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Pericarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15521** | click or scan EU-EC-10009058539 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15522** | click or scan EU-EC-10009058387 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **15523** | click or scan EU-EC-10009058036 | | 2021-06-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Fatal - **Results in Death**), Neuralgia (n/a - Fatal - **Results in Death**), Wound complication (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15524** | click or scan EU-EC-10009058009 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15525** | click or scan EU-EC-10009057465 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a - More in ICSR]) |
| **15526** | click or scan EU-EC-10009057423 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (8d - Fatal - **Results in Death**), Pulmonary embolism (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown]) |
| **15527** | click or scan EU-EC-10009056433 | | 2021-06-17 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15528** | click or scan EU-EC-10009056108 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15529 | click or scan EU-EC-10009056072 | | 2021-06-17 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 15530 | click or scan EU-EC-10009055805 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Angina pectoris (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15531 | click or scan EU-EC-10009055691 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Injection site pain (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15532 | click or scan EU-EC-10009055597 | | 2021-06-17 | Healthcare Professional | Non EEA | Not Specified | Female | Acute cardiac event (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15533 | click or scan EU-EC-10009055420 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Unknown - ), Syncope (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15534 | click or scan EU-EC-10009055152 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac flutter (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15535 | click or scan EU-EC-10009055076 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15536 | click or scan EU-EC-10009054569 | | 2021-06-17 | Non Healthcare Professional | EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15537 | click or scan EU-EC-10009054544 | | 2021-06-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15538 | click or scan EU-EC-10009054540 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic stroke (5d - Fatal - **Results in Death**), Thrombocytopenia (24d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 15539 | click or scan EU-EC-10009054311 | | 2021-06-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Aphonia (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling of body temperature change (n/a - Fatal - **Results in Death**), Listless (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Unknown - [n/a - n/a - Intramuscular]) |
| 15540 | click or scan EU-EC-10009054300 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15541 | click or scan EU-EC-10009054293 | | 2021-06-17 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15542 | click or scan EU-EC-10009054223 | | 2021-06-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Injection site pain (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15543 | click or scan EU-EC-10009053507 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15544 | click or scan EU-EC-10009053505 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 15545 | click or scan EU-EC-10009053449 | | 2021-06-17 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15546 | click or scan EU-EC-10009053246 | | 2021-06-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 15547 | click or scan EU-EC-10009052537 | | 2021-06-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15548 | click or scan EU-EC-10009052440 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15549 | click or scan EU-EC-10009052438 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 15550 | click or scan EU-EC-10009051865 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15551 | click or scan EU-EC-10009051854 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15552 | click or scan EU-EC-10009051815 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15553 | click or scan EU-EC-10009051801 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15554 | click or scan EU-EC-10009051782 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15555 | click or scan EU-EC-10009051427 | | 2021-06-17 | Healthcare Professional | EEA | 18-64 Years | Female | Death (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15556 | click or scan EU-EC-10009051063 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15557 | click or scan EU-EC-10009050581 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Dyskinesia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15558 | click or scan EU-EC-10009050573 | | 2021-06-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Bedridden (n/a - Fatal - **Results in Death**), Blood glucose fluctuation (n/a - Fatal - **Results in Death**), Blood iron decreased (n/a - Fatal - **Results in Death**), Cardiac failure (2d - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Eye movement disorder (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), International normalised ratio increased (n/a - Fatal - **Results in Death**), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Renal failure (2d - Fatal - **Results in Death**), Renal impairment (n/a - Fatal - **Results in Death**), Wheelchair user (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 15559 | click or scan EU-EC-10009050506 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Feeling cold (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15560 | click or scan EU-EC-10009050313 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Cough (0d - Fatal - **Results in Death**), Dyspnoea (6d - Recovered/Resolved With Sequelae - ), Pyrexia (5d - Fatal - **Results in Death**), Resuscitation (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 15561 | click or scan EU-EC-10009050235 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chronic obstructive pulmonary disease (n/a - Unknown - ), Concomitant disease aggravated (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15562 | click or scan EU-EC-10009049722 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 15563 | click or scan EU-EC-10009049656 | | 2021-06-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15564 | click or scan EU-EC-10009049561 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 15565 | click or scan EU-EC-10009049275 | | 2021-06-17 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15566 | click or scan EU-EC-10009049174 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Spinal compression fracture (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15567 | click or scan EU-EC-10009049034 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15568 | click or scan EU-EC-10009049032 | | 2021-06-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15569 | click or scan EU-EC-10009048858 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15570 | click or scan EU-EC-10009047761 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - ), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sinus tachycardia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15571 | click or scan EU-EC-10009047749 | | 2021-06-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15572 | click or scan EU-EC-10009047376 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15573 | click or scan EU-EC-10009047302 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15574 | click or scan EU-EC-10009047298 | | 2021-06-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15575 | click or scan EU-EC-10009047033 | | 2021-06-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15576 | click or scan EU-EC-10009047030 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15577 | click or scan EU-EC-10009046959 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15578** | click or scan EU-EC-10009046886 | | 2021-06-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Eyelid ptosis (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hemianopia (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15579** | click or scan EU-EC-10009046812 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15580** | click or scan EU-EC-10009046708 | | 2021-06-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15581** | click or scan EU-EC-10009046542 | | 2021-06-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15582** | click or scan EU-EC-10009046103 | | 2021-06-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Photophobia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **15583** | click or scan EU-EC-10009045038 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **15584** | click or scan EU-EC-10009045015 | | 2021-06-17 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (0d - Fatal - **Results in Death**), Cerebral haemorrhage (0d - Fatal - **Results in Death**), Eye movement disorder (0d - Fatal - **Results in Death**), Incontinence (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**), Shift to the left (0d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [TICLOPIDINE] (S - Antiplatelet therapy - Drug withdrawn - [n/a - n/a - Oral]) |
| **15585** | click or scan EU-EC-10009042613 | | 2021-06-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **15586** | click or scan EU-EC-10009044825 | | 2021-06-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15587 | click or scan EU-EC-10009044673 | | 2021-06-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Life Threatening), Asthenia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening), Hypersomnia (n/a - Fatal - **Results in Death**, Life Threatening), Large intestine perforation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 15588 | click or scan EU-EC-10009043953 | | 2021-06-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15589 | click or scan EU-EC-10009043652 | | 2021-06-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Venous thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15590 | click or scan EU-EC-10009043156 | | 2021-06-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Eye movement disorder (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nervousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure like phenomena (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15591 | click or scan EU-EC-10009042827 | | 2021-06-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15592 | click or scan EU-EC-10009041192 | | 2021-06-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**), Heart rate irregular (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15593 | click or scan EU-EC-10009041167 | | 2021-06-16 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lactic acidosis (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15594 | click or scan EU-EC-10009040713 | | 2021-06-16 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebral haemorrhage foetal (1d - Fatal - **Results in Death**, Other Medically Important Condition), Foetal death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15595 | click or scan EU-EC-10009040545 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15596 | click or scan EU-EC-10009039831 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 15597 | click or scan EU-EC-10009039088 | | 2021-06-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 15598 | click or scan EU-EC-10009038972 | | 2021-06-16 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15599 | click or scan EU-EC-10009038898 | | 2021-06-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15600 | click or scan EU-EC-10009038694 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15601 | click or scan EU-EC-10009038164 | | 2021-06-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle rigidity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tenderness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15602 | click or scan EU-EC-10009038012 | | 2021-06-16 | Healthcare Professional | EEA | More than 85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 15603 | click or scan EU-EC-10009038000 | | 2021-06-16 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - .6mL - Intramuscular]) |
| 15604 | click or scan EU-EC-10009037920 | | 2021-06-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | C-reactive protein increased (n/a - Unknown - ), CSF glucose increased (n/a - Unknown - Other Medically Important Condition), Completed suicide (n/a - Fatal - **Results in Death**), Dizziness postural (n/a - Recovered/Resolved - ), Hyperventilation (n/a - Unknown - ), Lip haemorrhage (n/a - Unknown - ), Mental disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Tetany (n/a - Unknown - ), Tremor (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15605 | click or scan EU-EC-10009037750 | | 2021-06-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15606** | click or scan EU-EC-10009037559 | | 2021-06-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **15607** | click or scan EU-EC-10009037446 | | 2021-06-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15608** | click or scan EU-EC-10009037405 | | 2021-06-16 | Healthcare Professional | EEA | 18-64 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **15609** | click or scan EU-EC-10009037293 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15610** | click or scan EU-EC-10009037273 | | 2021-06-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pulse abnormal (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **15611** | click or scan EU-EC-10009037106 | | 2021-06-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15612** | click or scan EU-EC-10009036981 | | 2021-06-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anal sphincter atony (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vertigo (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **15613** | click or scan EU-EC-10009036796 | | 2021-06-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15614** | click or scan EU-EC-10009036776 | | 2021-06-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **15615** | click or scan EU-EC-10009036743 | | 2021-06-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15616 | click or scan EU-EC-10009036722 | | 2021-06-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15617 | click or scan EU-EC-10009036630 | | 2021-06-16 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15618 | click or scan EU-EC-10009036604 | | 2021-06-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15619 | click or scan EU-EC-10009035983 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 15620 | click or scan EU-EC-10009035895 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15621 | click or scan EU-EC-10009035893 | | 2021-06-16 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15622 | click or scan EU-EC-10009035558 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (2d - Fatal - **Results in Death**), Thrombosis (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15623 | click or scan EU-EC-10009034916 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Haematuria (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 15624 | click or scan EU-EC-10009034740 | | 2021-06-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15625 | click or scan EU-EC-10009034706 | | 2021-06-16 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15626 | click or scan EU-EC-10009034440 | | 2021-06-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac infection (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15627 | click or scan EU-EC-10009034127 | | 2021-06-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 15628 | click or scan EU-EC-10009034041 | | 2021-06-16 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 15629 | click or scan EU-EC-10009033580 | | 2021-06-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Mobility decreased (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Red blood cell sedimentation rate increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15630 | click or scan EU-EC-10009033547 | | 2021-06-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (S - Body temperature increased - n/a - [n/a - 500mg - n/a]) |
| 15631 | click or scan EU-EC-10009033258 | | 2021-06-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (1wk - Unknown - ), Fibrosis (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammation (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia viral (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15632 | click or scan EU-EC-10009033112 | | 2021-06-16 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Medication error (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15633 | click or scan EU-EC-10009032013 | | 2021-06-16 | Healthcare Professional | EEA | More than 85 Years | Female | Asymptomatic COVID-19 (0d - Fatal - **Results in Death**), Vaccination failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 15634 | click or scan EU-EC-10009031675 | | 2021-06-16 | Healthcare Professional | EEA | More than 85 Years | Female | Oxygen saturation decreased (0d - Fatal - **Results in Death**), Tachycardia (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15635 | click or scan EU-EC-10009031325 | | 2021-06-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 15636 | click or scan EU-EC-10009030556 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15637** | click or scan EU-EC-10009030364 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Depressed mood (n/a - Fatal - **Results in Death**), Diarrhoea (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15638** | click or scan EU-EC-10009030222 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Male | Condition aggravated (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nephrotic syndrome (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **15639** | click or scan EU-EC-10009029552 | | 2021-06-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **15640** | click or scan EU-EC-10009029522 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - ), Critical illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (2d - Recovered/Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Retching (n/a - Unknown - ), Vaccination failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **15641** | click or scan EU-EC-10009029186 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Acute respiratory failure (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15642** | click or scan EU-EC-10009028572 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Body temperature abnormal (n/a - Not Recovered/Not Resolved - ), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Hospitalisation (n/a - Not Recovered/Not Resolved - ), Oxygen saturation abnormal (n/a - Not Recovered/Not Resolved - ), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - ), Oxygen therapy (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - ), Vaccination failure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **15643** | click or scan EU-EC-10009028352 | | 2021-06-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial injury (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **15644** | click or scan EU-EC-10009028274 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **15645** | click or scan EU-EC-10009028209 | | 2021-06-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Condition aggravated (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Disease recurrence (n/a - Unknown - ), Gastritis (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **15646** | click or scan EU-EC-10009027497 | | 2021-06-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15647 | click or scan EU-EC-10009027482 | | 2021-06-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Foetal death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15648 | click or scan EU-EC-10009027186 | | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15649 | click or scan EU-EC-10009027165 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Hypertension (7d - Not Recovered/Not Resolved - ), Meningorrhagia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), ELIQUIS [APIXABAN] (S - Atrial fibrillation - Dose not changed - [n/a - 2{DF} - Oral]) |
| 15650 | click or scan EU-EC-10009027140 | | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 15651 | click or scan EU-EC-10009027127 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Female | Diabetes mellitus inadequate control (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 15652 | click or scan EU-EC-10009027110 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 15653 | click or scan EU-EC-10009026967 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial thrombosis (n/a - Fatal - **Results in Death**), Embolism arterial (n/a - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 15654 | click or scan EU-EC-10009026880 | | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Male | Ileus (2d - Fatal - **Results in Death**), Mesenteric vein thrombosis (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15655 | click or scan EU-EC-10009026878 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15656 | click or scan EU-EC-10009026683 | | 2021-06-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse reaction (n/a - Unknown - ), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15657 | click or scan EU-EC-10009026362 |  | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15658 | click or scan EU-EC-10009026054 |  | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15659 | click or scan EU-EC-10009025596 |  | 2021-06-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15660 | click or scan EU-EC-10009025588 |  | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15661 | click or scan EU-EC-10009025580 |  | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15662 | click or scan EU-EC-10009025303 |  | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15663 | click or scan EU-EC-10009025300 |  | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (1h - Fatal - **Results in Death**), Sudden cardiac death (1h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15664 | click or scan EU-EC-10009025299 |  | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15665 | click or scan EU-EC-10009025123 |  | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15666 | click or scan EU-EC-10009024933 |  | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15667** | click or scan EU-EC-10009024927 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15668** | click or scan EU-EC-10009024872 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15669** | click or scan EU-EC-10009024871 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15670** | click or scan EU-EC-10009024790 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15671** | click or scan EU-EC-10009024530 | | 2021-06-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15672** | click or scan EU-EC-10009024528 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hypotension (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15673** | click or scan EU-EC-10009024523 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **15674** | click or scan EU-EC-10009024512 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15675** | click or scan EU-EC-10009024510 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15676** | click or scan EU-EC-10009024507 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15677 | click or scan EU-EC-10009024500 | | 2021-06-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Faecal vomiting (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15678 | click or scan EU-EC-10009024152 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Pelvic venous thrombosis (n/a - Fatal - **Results in Death**), Renal vein thrombosis (n/a - Fatal - **Results in Death**), Vena cava thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - .3mL - Intramuscular]) |
| 15679 | click or scan EU-EC-10009023747 | | 2021-06-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**), Coma (3d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Haemorrhage (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15680 | click or scan EU-EC-10009023745 | | 2021-06-15 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15681 | click or scan EU-EC-10009022886 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Bacterial infection (n/a - Fatal - **Results in Death**), Cytomegalovirus viraemia (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Idiopathic pulmonary fibrosis (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 15682 | click or scan EU-EC-10009022764 | | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15683 | click or scan EU-EC-10009022582 | | 2021-06-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Biopsy soft tissue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Brain compression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain scan abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain stem syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pathology test (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15684 | click or scan EU-EC-10009022161 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Polyuria (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15685 | click or scan EU-EC-10009022094 | | 2021-06-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15686 | click or scan EU-EC-10009022046 | | 2021-06-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15687 | click or scan EU-EC-10009021841 | | 2021-06-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15688 | click or scan EU-EC-10009021838 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15689 | click or scan EU-EC-10009021835 | | 2021-06-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Eating disorder (n/a - Unknown - Other Medically Important Condition), Fluid intake reduced (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15690 | click or scan EU-EC-10009021834 | | 2021-06-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 15691 | click or scan EU-EC-10009021809 | | 2021-06-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15692 | click or scan EU-EC-10009021070 | | 2021-06-15 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15693 | click or scan EU-EC-10009020938 | | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (10d - Fatal - **Results in Death**), Fatigue (10d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15694 | click or scan EU-EC-10009020372 | | 2021-06-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15695 | click or scan EU-EC-10009019823 | | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Female | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15696 | click or scan EU-EC-10009018088 | | 2021-06-15 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Pulmonary infarction (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15697** | click or scan EU-EC-10009017751 | | 2021-06-15 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (1d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **15698** | click or scan EU-EC-10009016961 | | 2021-06-14 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **15699** | click or scan EU-EC-10009016327 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15700** | click or scan EU-EC-10009016250 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15701** | click or scan EU-EC-10009016073 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Female | Autoimmune pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bone marrow failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15702** | click or scan EU-EC-10009015912 | | 2021-06-14 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Myocardial ischaemia (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **15703** | click or scan EU-EC-10009015875 | | 2021-06-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Akathisia (n/a - Fatal - **Results in Death**), Increased bronchial secretion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15704** | click or scan EU-EC-10009015291 | | 2021-06-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15705** | click or scan EU-EC-10009015089 | | 2021-06-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15706** | click or scan EU-EC-10009014287 | | 2021-06-14 | Non Healthcare Professional | EEA | 18-64 Years | Female | Post vaccination syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15707** | click or scan EU-EC-10009013983 | | 2021-06-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Balance disorder (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dizziness (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Syncope (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15708** | click or scan EU-EC-10009013977 | | 2021-06-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15709** | click or scan EU-EC-10009012635 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15710** | click or scan EU-EC-10009012581 | | 2021-06-14 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **15711** | click or scan EU-EC-10009012531 | | 2021-06-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15712** | click or scan EU-EC-10009012455 | | 2021-06-14 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **15713** | click or scan EU-EC-10009011985 | | 2021-06-14 | Healthcare Professional | Non EEA | Not Specified | Male | Chills (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15714** | click or scan EU-EC-10009011783 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (70d - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [5s - 1 {DF} - Intramuscular - More in ICSR]) |
| **15715** | click or scan EU-EC-10009011566 | | 2021-06-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15716** | click or scan EU-EC-10009011504 | | 2021-06-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Angiogram cerebral abnormal (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cerebral endovascular aneurysm repair (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral mass effect (n/a - Fatal - **Results in Death**), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**), Craniotomy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Laboratory test (n/a - Fatal - **Results in Death**), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Vasospasm (n/a - Fatal - **Results in Death**), Ventricular cisternostomy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15717** | click or scan EU-EC-10009011173 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15718** | click or scan EU-EC-10009010904 | | 2021-06-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15719** | click or scan EU-EC-10009010800 | | 2021-06-14 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **15720** | click or scan EU-EC-10009009984 | | 2021-06-14 | Healthcare Professional | EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15721** | click or scan EU-EC-10009009941 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15722** | click or scan EU-EC-10009009901 | | 2021-06-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15723** | click or scan EU-EC-10009009457 | | 2021-06-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15724** | click or scan EU-EC-10009009210 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pseudomonas infection (n/a - Unknown - Life Threatening), Respiratory failure (8d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stress cardiomyopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1s - 1 {DF} - Intramuscular - More in ICSR]) |
| **15725** | click or scan EU-EC-10009009080 | | 2021-06-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Balance disorder (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15726** | click or scan EU-EC-10009008964 | | 2021-06-14 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **15727** | click or scan EU-EC-10009008939 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15728 | click or scan EU-EC-10009008933 | | 2021-06-14 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15729 | click or scan EU-EC-10009008785 | | 2021-06-14 | Healthcare Professional | EEA | 18-64 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Injection site induration (n/a - Fatal - **Results in Death**), Injection site inflammation (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Injection site warmth (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 15730 | click or scan EU-EC-10009008524 | | 2021-06-14 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15731 | click or scan EU-EC-10009008207 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Not Recovered/Not Resolved - ), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Hypotension (n/a - Unknown - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (1d - Recovered/Resolved - ), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Sputum retention (n/a - Not Recovered/Not Resolved - ), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15732 | click or scan EU-EC-10009008070 | | 2021-06-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15733 | click or scan EU-EC-10009007544 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15734 | click or scan EU-EC-10009007497 | | 2021-06-14 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 15735 | click or scan EU-EC-10009007444 | | 2021-06-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Myalgia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15736 | click or scan EU-EC-10009007281 | | 2021-06-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15737 | click or scan EU-EC-10009007058 | | 2021-06-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15738 | click or scan EU-EC-10009006111 | | 2021-06-14 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15739 | click or scan EU-EC-10009006059 | | 2021-06-14 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15740 | click or scan EU-EC-10009005097 | | 2021-06-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15741 | click or scan EU-EC-10009005095 | | 2021-06-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15742 | click or scan EU-EC-10009003352 | | 2021-06-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15743 | click or scan EU-EC-10009003351 | | 2021-06-13 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15744 | click or scan EU-EC-10009002908 | | 2021-06-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15745 | click or scan EU-EC-10009001399 | | 2021-06-12 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (5d - Fatal - **Results in Death**), Cough (5d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Fatigue (2d - Fatal - **Results in Death**), Gait disturbance (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 15746 | click or scan EU-EC-10009001171 | | 2021-06-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Recovering/Resolving - ), Anosmia (n/a - Recovering/Resolving - ), Chills (n/a - Recovering/Resolving - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Recovering/Resolving - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15747 | click or scan EU-EC-10009001128 | | 2021-06-12 | Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15748 | click or scan EU-EC-10009000729 | | 2021-06-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15749 | click or scan EU-EC-10009000598 | | 2021-06-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (3d - Fatal - **Results in Death**), Peripheral artery thrombosis (n/a - Unknown - **Results in Death**), Peripheral ischaemia (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15750 | click or scan EU-EC-10009000579 | | 2021-06-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15751 | click or scan EU-EC-10009000566 | | 2021-06-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haematoma (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Migraine (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15752 | click or scan EU-EC-10009000307 | | 2021-06-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15753 | click or scan EU-EC-10009000272 | | 2021-06-12 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15754 | click or scan EU-EC-10008999317 | | 2021-06-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15755 | click or scan EU-EC-10008999301 | | 2021-06-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15756 | click or scan EU-EC-10008998877 | | 2021-06-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Unknown - **Results in Death**), Ventricular tachycardia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 15757 | click or scan EU-EC-10008998873 | | 2021-06-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anal incontinence (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Facial paralysis (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Facial paresis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Recovered/Resolved With Sequelae - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15758 | click or scan EU-EC-10008998860 | | 2021-06-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Brain injury (n/a - Fatal - **Results in Death**, Life Threatening), Headache (2d - Recovered/Resolved - **Results in Death**, Life Threatening), Myocardial infarction (1d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 15759 | click or scan EU-EC-10008998697 | | 2021-06-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain injury (n/a - Not Recovered/Not Resolved - **Results in Death**), Cytotoxic oedema (n/a - Unknown - **Results in Death**), Epistaxis (n/a - Unknown - **Results in Death**), Haemodynamic instability (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Hydrocephalus (n/a - Unknown - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pupil fixed (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Renal impairment (n/a - Unknown - **Results in Death**), Seizure (n/a - Unknown - **Results in Death**), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 15760 | click or scan EU-EC-10008998038 | | 2021-06-12 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Oral candidiasis (n/a - Unknown - **Results in Death**), Oral pain (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15761 | click or scan EU-EC-10008998024 | | 2021-06-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Apnoea (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial pressure increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Platelet count decreased (10d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Prothrombin level increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupil fixed (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Parenteral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15762 | click or scan EU-EC-10008998012 | | 2021-06-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ascites (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood bilirubin increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperplasia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Jaundice (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Joint swelling (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nephropathy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neutrophil count increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal infarct (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Splinter haemorrhages (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vasculitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 15763 | click or scan EU-EC-10008997785 | | 2021-06-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 15764 | click or scan EU-EC-10008997666 | | 2021-06-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Intestinal infarction (n/a - Unknown - **Results in Death**), Intestinal ischaemia (n/a - Unknown - **Results in Death**), Renal infarct (n/a - Fatal - **Results in Death**), Splenic infarction (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - n/a]) |
| 15765 | click or scan EU-EC-10008997588 | | 2021-06-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15766 | click or scan EU-EC-10008997553 | | 2021-06-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 15767 | click or scan EU-EC-10008997163 | | 2021-06-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15768** | click or scan EU-EC-10008997160 | | 2021-06-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **15769** | click or scan EU-EC-10008996779 | | 2021-06-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **15770** | click or scan EU-EC-10008996561 | | 2021-06-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial ischaemia (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **15771** | click or scan EU-EC-10008996229 | | 2021-06-12 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15772** | click or scan EU-EC-10008996182 | | 2021-06-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cholecystitis (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15773** | click or scan EU-EC-10008995563 | | 2021-06-12 | Healthcare Professional | EEA | 65-85 Years | Male | Adenocarcinoma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **15774** | click or scan EU-EC-10008995283 | | 2021-06-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Bronchitis (16d - Fatal - **Results in Death**), Cardiac failure (16d - Fatal - **Results in Death**), Dyspnoea (16d - Fatal - **Results in Death**), Haemoglobin increased (16d - Fatal - **Results in Death**), Polycythaemia (16d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **15775** | click or scan EU-EC-10008993041 | | 2021-06-12 | Healthcare Professional | EEA | More than 85 Years | Female | Cough (14d - Fatal - **Results in Death**), Dyspnoea (14d - Fatal - **Results in Death**), Pyrexia (14d - Fatal - **Results in Death**), SARS-CoV-2 test positive (14d - Fatal - **Results in Death**), Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **15776** | click or scan EU-EC-10008992491 | | 2021-06-12 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15777** | click or scan EU-EC-10008994031 | | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Female | Carotid artery thrombosis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancreatitis acute (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **15778** | click or scan EU-EC-10008993938 | | 2021-06-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15779 | click or scan EU-EC-10008993645 | | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral artery thrombosis (30d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (30d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyelonephritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 15780 | click or scan EU-EC-10008992187 | | 2021-06-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15781 | click or scan EU-EC-10008991751 | | 2021-06-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (16d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15782 | click or scan EU-EC-10008990862 | | 2021-06-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15783 | click or scan EU-EC-10008990791 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Apraxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15784 | click or scan EU-EC-10008990762 | | 2021-06-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15785 | click or scan EU-EC-10008990029 | | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Localised oedema (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15786 | click or scan EU-EC-10008990000 | | 2021-06-11 | Healthcare Professional | EEA | More than 85 Years | Female | Atypical pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15787 | click or scan EU-EC-10008989990 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15788 | click or scan EU-EC-10008989975 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Henoch-Schonlein purpura (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15789** | click or scan EU-EC-10008989911 |  | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]), [AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID] (S - Peritonitis - Drug withdrawn - [1 d - 2 {DF} - Intravenous (not otherwise specified)]), [IOMEPROL] (S - Peritonitis - Drug withdrawn - [n/a - 90mg - Intravenous (not otherwise specified)]), [KETAMINE, KETAMINE HYDROCHLORIDE] (S - Induction of anaesthesia - Drug withdrawn - [n/a - 50mg - Intravenous (not otherwise specified)]), [PARACETAMOL] (S - Peritonitis - Drug withdrawn - [1 d - 2 {DF} - Intravenous (not otherwise specified)]), [PHLOROGLUCINOL, PHLOROGLUCINOL DIHYDRATE] (S - Peritonitis - Drug withdrawn - [n/a - 80mg - Intravenous (not otherwise specified)]), [PROPOFOL] (S - Induction of anaesthesia - Drug withdrawn - [n/a - 400mg - Intravenous (not otherwise specified)]), [ROCURONIUM BROMIDE] (S - Endotracheal intubation - Drug withdrawn - [n/a - 50mg - Intravenous (not otherwise specified)]), [SUFENTANIL, SUFENTANIL CITRATE] (S - Induction of anaesthesia - Drug withdrawn - [n/a - 20ug - Intravenous (not otherwise specified)]), [SUXAMETHONIUM, SUXAMETHONIUM CHLORIDE, SUXAMETHONIUM CHLORIDE DIHYDRATE, SUXAMETHONIUM IODIDE] (S - Endotracheal intubation - Drug withdrawn - [n/a - 100mg - Intravenous (not otherwise specified)]) |
| **15790** | click or scan EU-EC-10008989890 |  | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **15791** | click or scan EU-EC-10008989889 |  | 2021-06-11 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15792** | click or scan EU-EC-10008989877 |  | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15793** | click or scan EU-EC-10008989784 |  | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1 d - 1 {DF} - Intramuscular]), [ANHYDROUS CYCLOPHOSPHAMIDE, CYCLOPHOSPHAMIDE, CYCLOPHOSPHAMIDE MONOHYDRATE] (S - n/a - n/a - [n/a - n/a - n/a]), [EPIRUBICIN, EPIRUBICIN HYDROCHLORIDE] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15794 | click or scan EU-EC-10008989783 | | 2021-06-11 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 15795 | click or scan EU-EC-10008989780 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - n/a]) |
| 15796 | click or scan EU-EC-10008989745 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15797 | click or scan EU-EC-10008989744 | | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebellar haematoma (1d - Fatal - **Results in Death**), Cerebral venous thrombosis (1d - Fatal - **Results in Death**), Disseminated intravascular coagulation (1d - Fatal - **Results in Death**), Portal vein thrombosis (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (5d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 15798 | click or scan EU-EC-10008989743 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 15799 | click or scan EU-EC-10008988228 | | 2021-06-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15800 | click or scan EU-EC-10008987970 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Syncope (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15801 | click or scan EU-EC-10008986887 | | 2021-06-11 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac failure (1mo - Fatal - **Results in Death**), Dysuria (1mo - Fatal - **Results in Death**), Oedema (1mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15802 | click or scan EU-EC-10008986483 | | 2021-06-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15803 | click or scan EU-EC-10008985665 | | 2021-06-11 | Healthcare Professional | EEA | More than 85 Years | Male | Guillain-Barre syndrome (7d - Fatal - **Results in Death**), Polyneuropathy (7d - Fatal - **Results in Death**), Quadriparesis (7d - Fatal - **Results in Death**), Respiratory failure (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15804** | click or scan EU-EC-10008985352 |  | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15805** | click or scan EU-EC-10008985336 |  | 2021-06-11 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Throat irritation (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **15806** | click or scan EU-EC-10008985330 |  | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Female | Circulatory collapse (0d - Fatal - **Results in Death**), Dizziness (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Gait disturbance (2d - Fatal - **Results in Death**), Nausea (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15807** | click or scan EU-EC-10008985255 |  | 2021-06-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15808** | click or scan EU-EC-10008984888 |  | 2021-06-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Blood glucose increased (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **15809** | click or scan EU-EC-10008984214 |  | 2021-06-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Aphonia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Hallucination, visual (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Hypophagia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Vertigo (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **15810** | click or scan EU-EC-10008984061 |  | 2021-06-11 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15811** | click or scan EU-EC-10008984037 |  | 2021-06-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Body temperature increased (n/a - Fatal - **Results in Death**), Bone pain (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Myeloid leukaemia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15812** | click or scan EU-EC-10008983872 |  | 2021-06-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15813 | click or scan EU-EC-10008983852 | | 2021-06-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain stem infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15814 | click or scan EU-EC-10008983199 | | 2021-06-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15815 | click or scan EU-EC-10008982203 | | 2021-06-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15816 | click or scan EU-EC-10008981647 | | 2021-06-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15817 | click or scan EU-EC-10008981385 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15818 | click or scan EU-EC-10008981063 | | 2021-06-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15819 | click or scan EU-EC-10008980808 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Ileus paralytic (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**), Pseudomembranous colitis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 15820 | click or scan EU-EC-10008979629 | | 2021-06-11 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15821 | click or scan EU-EC-10008979628 | | 2021-06-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 15822 | click or scan EU-EC-10008979199 | | 2021-06-10 | Healthcare Professional | Non EEA | Not Specified | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Cardiovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Headache (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15823 | click or scan EU-EC-10008978438 | | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastritis (n/a - Unknown - ), Heart rate abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Palpitations (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15824** | click or scan EU-EC-10008978397 |  | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral venous thrombosis (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Spontaneous haemorrhage (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular tachycardia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15825** | click or scan EU-EC-10008978308 |  | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| **15826** | click or scan EU-EC-10008978250 |  | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anosmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15827** | click or scan EU-EC-10008978243 |  | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15828** | click or scan EU-EC-10008978017 |  | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - 1 {DF} - n/a]) |
| **15829** | click or scan EU-EC-10008977479 |  | 2021-06-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Myalgia (15d - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - n/a]) |
| **15830** | click or scan EU-EC-10008977250 |  | 2021-06-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15831** | click or scan EU-EC-10008977195 |  | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Appendicitis (n/a - Fatal - **Results in Death**), Peritonitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15832** | click or scan EU-EC-10008976850 |  | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15833** | click or scan EU-EC-10008976552 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Capillary leak syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Polycythaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15834** | click or scan EU-EC-10008976074 | | 2021-06-10 | Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (2d - Fatal - **Results in Death**), Cerebral haemorrhage (2d - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (0d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15835** | click or scan EU-EC-10008976068 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15836** | click or scan EU-EC-10008975069 | | 2021-06-10 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **15837** | click or scan EU-EC-10008974809 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15838** | click or scan EU-EC-10008974490 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15839** | click or scan EU-EC-10008974466 | | 2021-06-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15840** | click or scan EU-EC-10008974465 | | 2021-06-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15841** | click or scan EU-EC-10008974353 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15842 | click or scan EU-EC-10008974055 |  | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cellulitis (n/a - Unknown - ), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15843 | click or scan EU-EC-10008973750 |  | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (15d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (15d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15844 | click or scan EU-EC-10008973742 |  | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Coronary artery thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15845 | click or scan EU-EC-10008973738 |  | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15846 | click or scan EU-EC-10008973725 |  | 2021-06-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15847 | click or scan EU-EC-10008973663 |  | 2021-06-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Slow speech (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15848 | click or scan EU-EC-10008973625 |  | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | Coma (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 15849 | click or scan EU-EC-10008972865 |  | 2021-06-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15850 | click or scan EU-EC-10008972858 |  | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15851 | click or scan EU-EC-10008972852 |  | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15852 | click or scan EU-EC-10008972714 |  | 2021-06-10 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15853** | click or scan EU-EC-10008972659 | | 2021-06-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **15854** | click or scan EU-EC-10008972655 | | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal infarct (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superficial vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ultrasound scan abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venous occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **15855** | click or scan EU-EC-10008972620 | | 2021-06-10 | Healthcare Professional | EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1 d - 1 {DF} - Intramuscular]) |
| **15856** | click or scan EU-EC-10008972557 | | 2021-06-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (1 d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - 1 {DF} - Intramuscular]) |
| **15857** | click or scan EU-EC-10008972544 | | 2021-06-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary thrombosis (42 d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| **15858** | click or scan EU-EC-10008972542 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| **15859** | click or scan EU-EC-10008972537 | | 2021-06-10 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15860** | click or scan EU-EC-10008972463 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [43d - 1 {DF} - Intramuscular]) |
| **15861** | click or scan EU-EC-10008972458 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1 {DF} - Intramuscular]) |
| **15862** | click or scan EU-EC-10008972417 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15863** | click or scan EU-EC-10008971743 | | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15864** | click or scan EU-EC-10008971596 | | 2021-06-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15865** | click or scan EU-EC-10008971479 | | 2021-06-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **15866** | click or scan EU-EC-10008971431 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15867** | click or scan EU-EC-10008971426 | | 2021-06-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15868** | click or scan EU-EC-10008971424 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Coronary artery thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**), Superficial vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15869** | click or scan EU-EC-10008971423 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **15870** | click or scan EU-EC-10008971420 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15871 | click or scan EU-EC-10008971419 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15872 | click or scan EU-EC-10008971417 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pelvic venous thrombosis (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15873 | click or scan EU-EC-10008971410 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15874 | click or scan EU-EC-10008971409 | | 2021-06-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15875 | click or scan EU-EC-10008971407 | | 2021-06-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Hypoxia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ), Respiratory failure (n/a - Fatal - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15876 | click or scan EU-EC-10008971377 | | 2021-06-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15877 | click or scan EU-EC-10008970931 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15878 | click or scan EU-EC-10008970904 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15879 | click or scan EU-EC-10008970869 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15880 | click or scan EU-EC-10008970862 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15881 | click or scan EU-EC-10008970858 | | 2021-06-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lip and/or oral cavity cancer recurrent (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mental impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |

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|---|---|---|---|---|---|---|---|---|---|
| 15882 | click or scan EU-EC-10008970648 | | 2021-06-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15883 | click or scan EU-EC-10008970475 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Illness (n/a - Not Recovered/Not Resolved - ), Lung infiltration (n/a - Not Recovered/Not Resolved - ), Shock (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15884 | click or scan EU-EC-10008969801 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15885 | click or scan EU-EC-10008969658 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**), Neurological symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15886 | click or scan EU-EC-10008968257 | | 2021-06-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15887 | click or scan EU-EC-10008968046 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15888 | click or scan EU-EC-10008968012 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15889 | click or scan EU-EC-10008968002 | | 2021-06-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aggression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15890 | click or scan EU-EC-10008967905 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Intentional overdose (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Toxicity to various agents (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15891 | click or scan EU-EC-10008967230 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15892 | click or scan EU-EC-10008967214 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Parkinson's disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15893 | click or scan EU-EC-10008967189 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15894 | click or scan EU-EC-10008967172 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15895 | click or scan EU-EC-10008966907 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15896 | click or scan EU-EC-10008966721 | | 2021-06-10 | Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 15897 | click or scan EU-EC-10008966026 | | 2021-06-10 | Healthcare Professional | EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Vertigo (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 15898 | click or scan EU-EC-10008965703 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15899 | click or scan EU-EC-10008965681 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15900 | click or scan EU-EC-10008965543 | | 2021-06-10 | Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15901 | click or scan EU-EC-10008965524 | | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15902 | click or scan EU-EC-10008965246 | | 2021-06-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15903 | click or scan EU-EC-10008965217 | | 2021-06-10 | Healthcare Professional | EEA | 18-64 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 15904 | click or scan EU-EC-10008965133 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritonitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15905 | click or scan EU-EC-10008965130 | | 2021-06-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15906 | click or scan EU-EC-10008965076 | | 2021-06-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperkalaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Influenza like illness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Retching (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vision blurred (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15907 | click or scan EU-EC-10008965034 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [14d - n/a - Intramuscular]) |
| 15908 | click or scan EU-EC-10008964996 | | 2021-06-10 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15909 | click or scan EU-EC-10008964945 | | 2021-06-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15910 | click or scan EU-EC-10008964779 | | 2021-06-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Mental impairment (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15911 | click or scan EU-EC-10008964639 | | 2021-06-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blindness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Serratia infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15912** | click or scan EU-EC-10008964158 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Poor quality sleep (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15913** | click or scan EU-EC-10008964092 | | 2021-06-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleuritic pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vascular graft thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **15914** | click or scan EU-EC-10008963841 | | 2021-06-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15915** | click or scan EU-EC-10008963523 | | 2021-06-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15916** | click or scan EU-EC-10008963077 | | 2021-06-09 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **15917** | click or scan EU-EC-10008962910 | | 2021-06-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| **15918** | click or scan EU-EC-10008962736 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Concomitant disease aggravated (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown]) |
| **15919** | click or scan EU-EC-10008962654 | | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | BRILIQUE 60 MG FILM-COATED TABLETS [TICAGRELOR] (S - Angioplasty - Dose not changed - [n/a - 90mg - Oral]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), [ACETYLSALICYLIC ACID] (S - n/a - Dose not changed - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15920 | click or scan EU-EC-10008962632 | | 2021-06-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15921 | click or scan EU-EC-10008962404 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Cerebral haemorrhage (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15922 | click or scan EU-EC-10008961581 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tremor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15923 | click or scan EU-EC-10008961233 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15924 | click or scan EU-EC-10008960659 | | 2021-06-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 15925 | click or scan EU-EC-10008960601 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac tamponade (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Injection site erythema (n/a - Fatal - **Results in Death**), Injection site inflammation (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Injection site warmth (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15926 | click or scan EU-EC-10008960063 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (37d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Incorrect route of product administration (1d - Fatal - **Results in Death**), Limb injury (n/a - Fatal - **Results in Death**), Mobility decreased (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**), Thrombosis (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous - More in ICSR]) |
| 15927 | click or scan EU-EC-10008959773 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15928 | click or scan EU-EC-10008959741 | | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15929 | click or scan EU-EC-10008959459 | | 2021-06-09 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15930** | click or scan EU-EC-10008959447 | | 2021-06-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15931** | click or scan EU-EC-10008959282 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **15932** | click or scan EU-EC-10008959240 | | 2021-06-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15933** | click or scan EU-EC-10008959166 | | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]), [ACENOCOUMAROL] (S - Thrombosis prophylaxis - n/a - [n/a - n/a - Oral]) |
| **15934** | click or scan EU-EC-10008959156 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute disseminated encephalomyelitis (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain stem infarction (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular disorder (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemia (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Osmotic demyelination syndrome (66d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15935** | click or scan EU-EC-10008959120 | | 2021-06-09 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]) |
| **15936** | click or scan EU-EC-10008959107 | | 2021-06-09 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haematoma (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **15937** | click or scan EU-EC-10008959102 | | 2021-06-09 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15938** | click or scan EU-EC-10008959006 | | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Influenza (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15939 | click or scan EU-EC-10008959002 |  | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Visual impairment (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15940 | click or scan EU-EC-10008958957 |  | 2021-06-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15941 | click or scan EU-EC-10008958955 |  | 2021-06-09 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15942 | click or scan EU-EC-10008958954 |  | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15943 | click or scan EU-EC-10008958946 |  | 2021-06-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15944 | click or scan EU-EC-10008958945 |  | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15945 | click or scan EU-EC-10008958362 |  | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15946 | click or scan EU-EC-10008958038 |  | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15947 | click or scan EU-EC-10008957765 |  | 2021-06-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral thrombosis (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15948 | click or scan EU-EC-10008957703 |  | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15949 | click or scan EU-EC-10008957671 |  | 2021-06-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **15950** | click or scan EU-EC-10008957401 | | 2021-06-09 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **15951** | click or scan EU-EC-10008957236 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (2d - Fatal - **Results in Death**), Influenza like illness (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15952** | click or scan EU-EC-10008957091 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Presyncope (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **15953** | click or scan EU-EC-10008957063 | | 2021-06-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **15954** | click or scan EU-EC-10008957059 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [ENOXAPARIN SODIUM] (S - Myocardial bridging - Unknown - [9d - 80mg - Subcutaneous]) |
| **15955** | click or scan EU-EC-10008957041 | | 2021-06-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15956** | click or scan EU-EC-10008957036 | | 2021-06-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15957** | click or scan EU-EC-10008957033 | | 2021-06-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **15958** | click or scan EU-EC-10008957029 | | 2021-06-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15959 | click or scan EU-EC-10008956972 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15960 | click or scan EU-EC-10008956805 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspepsia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid retention (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fungaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Poor quality sleep (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Product dose omission issue (n/a - Unknown - ), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Supraventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15961 | click or scan EU-EC-10008956767 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15962 | click or scan EU-EC-10008956424 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (37d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (37d - Fatal - **Results in Death**), Feeling abnormal (37d - Fatal - **Results in Death**), Myocardial infarction (37d - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral swelling (37d - Fatal - **Results in Death**), Pyrexia (37d - Fatal - **Results in Death**), Thrombosis (37d - Fatal - **Results in Death**, Other Medically Important Condition), Transient ischaemic attack (37d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15963 | click or scan EU-EC-10008956265 | | 2021-06-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 15964 | click or scan EU-EC-10008956155 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (3d - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (3d - Fatal - **Results in Death**), Pneumonia aspiration (3d - Fatal - **Results in Death**), Sepsis (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15965 | click or scan EU-EC-10008956109 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 15966 | click or scan EU-EC-10008956064 | | 2021-06-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery occlusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 15967 | click or scan EU-EC-10008956028 | | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15968 | click or scan EU-EC-10008955767 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Female | Asymptomatic COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 15969 | click or scan EU-EC-10008954854 | | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 15970 | click or scan EU-EC-10008953910 | | 2021-06-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Anal incontinence (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperventilation (n/a - Unknown - Caused/Prolonged Hospitalisation), Neoplasm progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Other Medically Important Condition), Red blood cell count decreased (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition), White blood cell count abnormal (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15971 | click or scan EU-EC-10008953861 | | 2021-06-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 15972 | click or scan EU-EC-10008953646 | | 2021-06-09 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea haemorrhagic (n/a - Fatal - **Results in Death**), Diverticulitis (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 15973 | click or scan EU-EC-10008953622 | | 2021-06-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Depressed mood (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Incontinence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Panic reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 15974 | click or scan EU-EC-10008952141 | | 2021-06-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15975 | click or scan EU-EC-10008952017 | | 2021-06-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Atrial fibrillation (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cerebral haemorrhage (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Coma (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Confusional state (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Headache (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pupillary reflex impaired (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pupils unequal (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Tachyarrhythmia (5d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 15976 | click or scan EU-EC-10008951834 | | 2021-06-09 | Healthcare Professional | EEA | 18-64 Years | Female | Blood pressure increased (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 15977 | click or scan EU-EC-10008951828 |  | 2021-06-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 15978 | click or scan EU-EC-10008951638 |  | 2021-06-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 15979 | click or scan EU-EC-10008950468 |  | 2021-06-09 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (7h - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 15980 | click or scan EU-EC-10008950310 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 15981 | click or scan EU-EC-10008950053 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory acidosis (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15982 | click or scan EU-EC-10008950029 |  | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 15983 | click or scan EU-EC-10008950022 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 15984 | click or scan EU-EC-10008949719 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate abnormal (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15985** | click or scan EU-EC-10008949539 |  | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diabetic complication (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercalcaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - Intramuscular]) |
| **15986** | click or scan EU-EC-10008949429 |  | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1 d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (77 d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15987** | click or scan EU-EC-10008949427 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **15988** | click or scan EU-EC-10008948995 |  | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1 d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (2 d - Fatal - **Results in Death**), Musculoskeletal discomfort (2 d - Fatal - **Results in Death**), Nasopharyngitis (2 d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **15989** | click or scan EU-EC-10008948870 |  | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1 d - Fatal - **Results in Death**, Other Medically Important Condition), Lung disorder (1 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (1 d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15990** | click or scan EU-EC-10008948495 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15991** | click or scan EU-EC-10008947977 |  | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (1 d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - **Results in Death**), Injection site erythema (n/a - Fatal - **Results in Death**), Injection site pruritus (n/a - Fatal - **Results in Death**), Injection site reaction (n/a - Fatal - **Results in Death**), Injection site swelling (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Skin reaction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **15992** | click or scan EU-EC-10008947948 |  | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pH decreased (n/a - Fatal - **Results in Death**), Carbon dioxide increased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Tidal volume decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| **15993** | click or scan EU-EC-10008947847 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **15994** | click or scan EU-EC-10008947631 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac disorder (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coronary arterial stent insertion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased interest (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15995** | click or scan EU-EC-10008947593 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **15996** | click or scan EU-EC-10008947513 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15997** | click or scan EU-EC-10008947403 | | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute cardiac event (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **15998** | click or scan EU-EC-10008947362 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Gastrointestinal haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **15999** | click or scan EU-EC-10008947183 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (86d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (86d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16000** | click or scan EU-EC-10008947059 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16001** | click or scan EU-EC-10008946827 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16002** | click or scan EU-EC-10008946684 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (1d - Unknown - Life Threatening), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16003** | click or scan EU-EC-10008946663 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16004** | click or scan EU-EC-10008946653 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16005** | click or scan EU-EC-10008946650 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16006** | click or scan EU-EC-10008946610 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dehydration (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16007** | click or scan EU-EC-10008946547 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16008** | click or scan EU-EC-10008946523 | | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16009** | click or scan EU-EC-10008946508 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16010** | click or scan EU-EC-10008946506 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16011** | click or scan EU-EC-10008946395 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16012** | click or scan EU-EC-10008946226 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16013** | click or scan<br>EU-EC-10008946133 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Bacterial infection (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Blood culture positive (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Catheter placement (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid replacement (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Gram stain positive (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Heparin-induced thrombocytopenia test (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Lung assist device therapy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Prone position (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Transfusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16014** | click or scan<br>EU-EC-10008946085 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **16015** | click or scan<br>EU-EC-10008946076 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16016** | click or scan<br>EU-EC-10008945720 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16017** | click or scan<br>EU-EC-10008945571 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16018** | click or scan EU-EC-10008945090 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| **16019** | click or scan EU-EC-10008945066 | | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Coma (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Ischaemia (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **16020** | click or scan EU-EC-10008944993 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **16021** | click or scan EU-EC-10008944900 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **16022** | click or scan EU-EC-10008944857 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16023** | click or scan EU-EC-10008944846 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Hypoglycaemia (1d - Recovered/Resolved With Sequelae - ), Respiratory distress (n/a - Fatal - **Results in Death**), Wrong product administered (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), NOVORAPID FLEXPEN [INSULIN ASPART] (S - Diabetes mellitus - Drug withdrawn - [1d - 12[iU] - Subcutaneous]) |
| **16024** | click or scan EU-EC-10008944841 | | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary vasculitis (n/a - Fatal - **Results in Death**), Renal vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular]) |
| **16025** | click or scan EU-EC-10008944808 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (37d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (37d - Fatal - **Results in Death**), Pain (37d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16026** | click or scan EU-EC-10008944807 | | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16027** | click or scan EU-EC-10008944738 | | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16028 | click or scan EU-EC-10008944733 |  | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16029 | click or scan EU-EC-10008944729 |  | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cough (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16030 | click or scan EU-EC-10008944728 |  | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Male | Gastrointestinal necrosis (3d - Fatal - **Results in Death**), Thrombosis (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16031 | click or scan EU-EC-10008944727 |  | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blood glucose abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16032 | click or scan EU-EC-10008944725 |  | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16033 | click or scan EU-EC-10008944685 |  | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16034 | click or scan EU-EC-10008944677 |  | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Hyperkalaemia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16035 | click or scan EU-EC-10008944648 |  | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16036 | click or scan EU-EC-10008944645 |  | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16037 | click or scan EU-EC-10008944637 |  | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16038 | click or scan EU-EC-10008944567 |  | 2021-06-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16039 | click or scan EU-EC-10008944560 |  | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16040 | click or scan EU-EC-10008944556 |  | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16041 | click or scan EU-EC-10008944542 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16042 | click or scan EU-EC-10008944431 |  | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16043 | click or scan EU-EC-10008944427 |  | 2021-06-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Enteritis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16044 | click or scan EU-EC-10008944385 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16045 | click or scan EU-EC-10008944372 |  | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16046 | click or scan EU-EC-10008944340 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16047 | click or scan EU-EC-10008944293 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 16048 | click or scan EU-EC-10008944269 |  | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16049 | click or scan EU-EC-10008944210 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concussion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Traumatic haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16050 | click or scan EU-EC-10008944027 |  | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16051 | click or scan EU-EC-10008944003 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 16052 | click or scan EU-EC-10008943933 |  | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| 16053 | click or scan EU-EC-10008943850 |  | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (3d - Unknown - ), Pulmonary pain (3d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 16054 | click or scan EU-EC-10008943832 |  | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16055 | click or scan EU-EC-10008943808 |  | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16056 | click or scan EU-EC-10008943654 |  | 2021-06-08 | Healthcare Professional | EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebellar haemorrhage (n/a - Fatal - **Results in Death**), Coma scale abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Dermatitis exfoliative generalised (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Systolic hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16057 | click or scan EU-EC-10008943567 |  | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16058 | click or scan EU-EC-10008943518 |  | 2021-06-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16059 | click or scan EU-EC-10008943516 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16060 | click or scan EU-EC-10008943498 | | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cognitive disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Erysipelas (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fluid retention (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypersomnia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Skin disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Skin wound (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vaccination site erythema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination site swelling (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16061 | click or scan EU-EC-10008943496 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16062 | click or scan EU-EC-10008943490 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16063 | click or scan EU-EC-10008943484 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16064 | click or scan EU-EC-10008942956 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16065 | click or scan EU-EC-10008942530 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16066 | click or scan EU-EC-10008942398 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 16067 | click or scan EU-EC-10008942312 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16068** | click or scan EU-EC-10008942285 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16069** | click or scan EU-EC-10008942226 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (10d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (10d - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**), Respiratory disorder (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16070** | click or scan EU-EC-10008942189 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16071** | click or scan EU-EC-10008941848 | | 2021-06-08 | Healthcare Professional | EEA | More than 85 Years | Male | Abnormal behaviour (n/a - Fatal - **Results in Death**, Life Threatening), Agitation (n/a - Fatal - **Results in Death**, Life Threatening), Anaemia (n/a - Fatal - **Results in Death**, Life Threatening), Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), Balance disorder (n/a - Fatal - **Results in Death**, Life Threatening), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Nervous system disorder (n/a - Fatal - **Results in Death**, Life Threatening), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening), Pallor (n/a - Fatal - **Results in Death**, Life Threatening), Speech disorder (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16072** | click or scan EU-EC-10008941769 | | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Microembolism (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Myocardial necrosis (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16073** | click or scan EU-EC-10008941692 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16074** | click or scan EU-EC-10008941172 | | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **16075** | click or scan EU-EC-10008940884 | | 2021-06-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16076** | click or scan EU-EC-10008940853 | | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16077** | click or scan EU-EC-10008940486 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16078** | click or scan EU-EC-10008940478 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| **16079** | click or scan EU-EC-10008940459 | | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (4d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16080** | click or scan EU-EC-10008940438 | | 2021-06-08 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **16081** | click or scan EU-EC-10008940362 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16082** | click or scan EU-EC-10008940061 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16083** | click or scan EU-EC-10008939677 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16084** | click or scan EU-EC-10008939370 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral ischaemia (5d - Fatal - **Results in Death**, Other Medically Important Condition), Generalised tonic-clonic seizure (5d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (5d - Fatal - **Results in Death**), Lactic acidosis (5d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (5d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16085** | click or scan EU-EC-10008939157 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pyrexia (3d - Fatal - **Results in Death**), Respiratory disorder (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **16086** | click or scan EU-EC-10008938655 | | 2021-06-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16087** | click or scan EU-EC-10008938530 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anosmia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16088** | click or scan EU-EC-10008938450 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Condition aggravated (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| **16089** | click or scan EU-EC-10008938373 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Lacrimation increased (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**, Life Threatening), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Rhinorrhoea (n/a - Fatal - **Results in Death**, Life Threatening), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **16090** | click or scan EU-EC-10008938342 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **16091** | click or scan EU-EC-10008938262 | | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Male | Acute pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16092** | click or scan EU-EC-10008938178 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **16093** | click or scan EU-EC-10008938036 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16094** | click or scan EU-EC-10008937812 | | 2021-06-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16095** | click or scan EU-EC-10008937753 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16096** | click or scan EU-EC-10008937729 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16097** | click or scan EU-EC-10008937484 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16098 | click or scan EU-EC-10008937483 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16099 | click or scan EU-EC-10008937482 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16100 | click or scan EU-EC-10008937398 | | 2021-06-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16101 | click or scan EU-EC-10008937367 | | 2021-06-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16102 | click or scan EU-EC-10008937116 | | 2021-06-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 16103 | click or scan EU-EC-10008936966 | | 2021-06-08 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 16104 | click or scan EU-EC-10008936958 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| 16105 | click or scan EU-EC-10008936549 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonitis (41d - Fatal - **Results in Death**), Respiratory failure (41d - Fatal - **Results in Death**), Septic shock (41d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a]) |
| 16106 | click or scan EU-EC-10008934487 | | 2021-06-08 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 16107 | click or scan EU-EC-10008936166 | | 2021-06-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Ageusia (n/a - Unknown - ), Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Disability (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Dysarthria (n/a - Unknown - ), Dysgeusia (n/a - Unknown - ), Dyskinesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Eating disorder (n/a - Not Recovered/Not Resolved - Disabling), Hand deformity (n/a - Unknown - Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - ), Impaired work ability (n/a - Not Recovered/Not Resolved - Disabling), Movement disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Peripheral swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Throat lesion (n/a - Unknown - ), Vomiting (n/a - Unknown - ), Weight decreased (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16108 | click or scan EU-EC-10008936145 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16109 | click or scan EU-EC-10008936103 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16110 | click or scan EU-EC-10008936047 | | 2021-06-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16111 | click or scan EU-EC-10008936036 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Encephalopathy (4d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised tonic-clonic seizure (4d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16112 | click or scan EU-EC-10008936035 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16113 | click or scan EU-EC-10008935820 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16114 | click or scan EU-EC-10008935748 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16115 | click or scan EU-EC-10008935740 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16116 | click or scan EU-EC-10008935705 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16117 | click or scan EU-EC-10008935702 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16118 | click or scan EU-EC-10008935686 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Vaccination site erythema (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 16119 | click or scan EU-EC-10008935603 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16120 | click or scan EU-EC-10008935596 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypoaesthesia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16121 | click or scan EU-EC-10008935594 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Electrolyte imbalance (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Malnutrition (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16122 | click or scan EU-EC-10008935522 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose fluctuation (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16123 | click or scan EU-EC-10008935519 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hyperventilation (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Muscle twitching (1d - Fatal - **Results in Death**), Posture abnormal (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16124 | click or scan EU-EC-10008935456 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16125 | click or scan EU-EC-10008935441 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16126 | click or scan EU-EC-10008935439 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Recovering/Resolving - ), Malaise (n/a - Recovered/Resolved - ), Oropharyngeal pain (n/a - Recovering/Resolving - ), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16127 | click or scan EU-EC-10008935273 | | 2021-06-07 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16128 | click or scan EU-EC-10008935083 | | 2021-06-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous]) |
| 16129 | click or scan EU-EC-10008935056 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral disorder (1d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Lung disorder (1d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal disorder (1d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16130 | click or scan EU-EC-10008935048 | | 2021-06-07 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 16131 | click or scan EU-EC-10008934842 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Toxic shock syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16132 | click or scan EU-EC-10008934709 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Gastroenteritis (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16133 | click or scan EU-EC-10008934244 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Meningococcal bacteraemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 16134 | click or scan EU-EC-10008934209 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Vomiting (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16135 | click or scan EU-EC-10008933824 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 16136 | click or scan EU-EC-10008933607 | | 2021-06-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16137 | click or scan EU-EC-10008933486 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Influenza like illness (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16138 | click or scan EU-EC-10008933185 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16139 | click or scan EU-EC-10008933118 | | 2021-06-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Overdose (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |
| 16140 | click or scan EU-EC-10008933049 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neuromyotonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 16141 | click or scan EU-EC-10008933037 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16142 | click or scan EU-EC-10008933029 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Posture abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16143 | click or scan EU-EC-10008933008 | | 2021-06-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Basilar artery thrombosis (n/a - Not Recovered/Not Resolved - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16144 | click or scan EU-EC-10008933004 | | 2021-06-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16145 | click or scan EU-EC-10008932849 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16146 | click or scan EU-EC-10008932222 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (10d - Fatal - **Results in Death**), Pulmonary hypertension (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16147 | click or scan EU-EC-10008932087 | | 2021-06-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16148 | click or scan EU-EC-10008931988 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16149 | click or scan EU-EC-10008931948 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16150 | click or scan EU-EC-10008931922 |  | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16151 | click or scan EU-EC-10008931842 |  | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16152 | click or scan EU-EC-10008931738 |  | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injection site pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16153 | click or scan EU-EC-10008931701 |  | 2021-06-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16154 | click or scan EU-EC-10008931632 |  | 2021-06-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 16155 | click or scan EU-EC-10008931585 |  | 2021-06-07 | Healthcare Professional | EEA | 18-64 Years | Female | Cold type haemolytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemolytic anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16156 | click or scan EU-EC-10008931547 |  | 2021-06-07 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 16157 | click or scan EU-EC-10008931424 |  | 2021-06-07 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16158 | click or scan EU-EC-10008931392 |  | 2021-06-07 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| 16159 | click or scan EU-EC-10008929469 |  | 2021-06-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16160 | click or scan EU-EC-10008929129 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 16161 | click or scan EU-EC-10008928426 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16162 | click or scan EU-EC-10008928257 | | 2021-06-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16163 | click or scan EU-EC-10008928135 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16164 | click or scan EU-EC-10008928134 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16165 | click or scan EU-EC-10008928125 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16166 | click or scan EU-EC-10008926544 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16167 | click or scan EU-EC-10008926338 | | 2021-06-07 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16168 | click or scan EU-EC-10008926142 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Male | Generalised tonic-clonic seizure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16169 | click or scan EU-EC-10008925930 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16170 | click or scan EU-EC-10008925825 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Male | Gastric ulcer haemorrhage (11d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16171 | click or scan EU-EC-10008925574 | | 2021-06-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 16172 | click or scan EU-EC-10008925489 | | 2021-06-07 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16173 | click or scan EU-EC-10008925408 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16174 | click or scan EU-EC-10008925071 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Polycythaemia vera - Not applicable - [n/a - n/a - n/a]) |
| 16175 | click or scan EU-EC-10008925000 | | 2021-06-07 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**), Drug ineffective (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16176 | click or scan EU-EC-10008924999 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (13d - Fatal - **Results in Death**), Diarrhoea (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16177 | click or scan EU-EC-10008924911 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Carotid artery thrombosis (n/a - Fatal - **Results in Death**), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebral mass effect (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 16178 | click or scan EU-EC-10008924899 | | 2021-06-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16179 | click or scan EU-EC-10008924667 | | 2021-06-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16180** | click or scan EU-EC-10008922044 | | 2021-06-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Unknown - ), Chills (n/a - Unknown - ), Headache (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Product dose omission issue (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Tachycardia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16181** | click or scan EU-EC-10008921799 | | 2021-06-06 | Healthcare Professional | EEA | 65-85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **16182** | click or scan EU-EC-10008921792 | | 2021-06-06 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **16183** | click or scan EU-EC-10008921772 | | 2021-06-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16184** | click or scan EU-EC-10008919409 | | 2021-06-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac ventricular thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16185** | click or scan EU-EC-10008919370 | | 2021-06-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Diabetic ketoacidosis (n/a - Unknown - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **16186** | click or scan EU-EC-10008918858 | | 2021-06-05 | Healthcare Professional | Non EEA | Not Specified | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16187** | click or scan EU-EC-10008918744 | | 2021-06-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Brain cancer metastatic (n/a - Unknown - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Delirium (n/a - Not Recovered/Not Resolved - **Results in Death**), Disorientation (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Lung neoplasm malignant (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (65d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **16188** | click or scan EU-EC-10008918315 | | 2021-06-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16189** | click or scan EU-EC-10008918116 | | 2021-06-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cold sweat (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in jaw (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16190** | click or scan EU-EC-10008918092 | | 2021-06-05 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16191** | click or scan EU-EC-10008918057 | | 2021-06-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16192** | click or scan EU-EC-10008917681 | | 2021-06-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (69d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16193** | click or scan EU-EC-10008917378 | | 2021-06-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16194** | click or scan EU-EC-10008917288 | | 2021-06-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Infective pulmonary exacerbation of cystic fibrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16195** | click or scan EU-EC-10008917287 | | 2021-06-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden unexplained death in epilepsy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16196** | click or scan EU-EC-10008917257 | | 2021-06-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **16197** | click or scan EU-EC-10008917249 | | 2021-06-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute cardiac event (n/a - Unknown - **Results in Death**), Embolism (n/a - Unknown - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **16198** | click or scan EU-EC-10008917068 | | 2021-06-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Recovered/Resolved - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Recovered/Resolved - **Results in Death**), Eructation (n/a - Recovered/Resolved - **Results in Death**), Myocardial infarction (38d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16199** | click or scan EU-EC-10008916016 | | 2021-06-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**), Drooling (n/a - Unknown - **Results in Death**), Gastrointestinal carcinoma (n/a - Unknown - **Results in Death**), Nasal congestion (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16200** | click or scan EU-EC-10008914713 | | 2021-06-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Oropharyngeal pain (n/a - Unknown - **Results in Death**), Retinal exudates (n/a - Unknown - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16201** | click or scan EU-EC-10008914585 | | 2021-06-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac murmur (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Mitral valve incompetence (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **16202** | click or scan EU-EC-10008914579 | | 2021-06-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Pain in extremity (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Skin ulcer (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16203** | click or scan EU-EC-10008914556 | | 2021-06-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16204** | click or scan EU-EC-10008914400 | | 2021-06-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Deep vein thrombosis (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16205** | click or scan EU-EC-10008914394 | | 2021-06-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Maternal exposure during pregnancy (n/a - Unknown - **Results in Death**, Congenital Anomaly), Neural tube defect (n/a - Fatal - **Results in Death**, Congenital Anomaly) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16206** | click or scan EU-EC-10008914059 | | 2021-06-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16207** | click or scan EU-EC-10008914043 | | 2021-06-05 | Healthcare Professional | EEA | 18-64 Years | Male | Drowning (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16208** | click or scan EU-EC-10008914024 | | 2021-06-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Unknown - ), Hyperventilation (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16209 | click or scan EU-EC-10008913947 | | 2021-06-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16210 | click or scan EU-EC-10008913695 | | 2021-06-05 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 16211 | click or scan EU-EC-10008913499 | | 2021-06-05 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Coma (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16212 | click or scan EU-EC-10008911180 | | 2021-06-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia (8d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16213 | click or scan EU-EC-10008912731 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - ), Feeling abnormal (n/a - Not Recovered/Not Resolved - ), Hot flush (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16214 | click or scan EU-EC-10008912497 | | 2021-06-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Haemodynamic instability (n/a - Unknown - Other Medically Important Condition), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypothermia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Unknown - Other Medically Important Condition), Lung abscess (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Myocardial ischaemia (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 16215 | click or scan EU-EC-10008912144 | | 2021-06-04 | Healthcare Professional | Non EEA | Not Specified | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16216 | click or scan EU-EC-10008912131 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16217 | click or scan EU-EC-10008911937 | | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Female | Immune thrombocytopenia (2d - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16218 | click or scan EU-EC-10008911815 | | 2021-06-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 16219 | click or scan EU-EC-10008911294 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16220 | click or scan EU-EC-10008910805 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Food refusal (n/a - Unknown - **Results in Death**), Somnolence (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16221 | click or scan EU-EC-10008910745 | | 2021-06-04 | Healthcare Professional | Non EEA | Not Specified | Male | Coagulopathy (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16222 | click or scan EU-EC-10008910652 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16223 | click or scan EU-EC-10008910370 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16224 | click or scan EU-EC-10008910222 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16225 | click or scan EU-EC-10008907925 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16226 | click or scan EU-EC-10008907499 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Embolism (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16227 | click or scan EU-EC-10008907367 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Unknown - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16228 | click or scan EU-EC-10008907363 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16229 | click or scan EU-EC-10008907304 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16230 | click or scan EU-EC-10008907288 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16231 | click or scan EU-EC-10008907234 | | 2021-06-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16232 | click or scan EU-EC-10008907178 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abdominal tenderness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal oedema (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoperitoneum (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Photopsia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic infarction (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vision blurred (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16233 | click or scan EU-EC-10008907158 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Agitation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Brain herniation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16234 | click or scan EU-EC-10008907140 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (2d - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16235 | click or scan EU-EC-10008907112 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening), Peripheral artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16236 | click or scan EU-EC-10008906974 | | 2021-06-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16237 | click or scan EU-EC-10008905889 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cold sweat (n/a - Recovered/Resolved - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16238 | click or scan EU-EC-10008905842 | | 2021-06-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate irregular (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a]) |
| 16239 | click or scan EU-EC-10008905740 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16240 | click or scan EU-EC-10008905737 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Acute abdomen (n/a - Not Recovered/Not Resolved - **Results in Death**), Blood glucose decreased (n/a - Not Recovered/Not Resolved - **Results in Death**), Blood lactic acid increased (n/a - Not Recovered/Not Resolved - **Results in Death**), Colitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**), Listless (n/a - Unknown - **Results in Death**), Metabolic acidosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Neutrophilia (n/a - Not Recovered/Not Resolved - **Results in Death**), Pancreatitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16241 | click or scan EU-EC-10008905657 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - **Results in Death**), Cardiac failure (n/a - Not Recovered/Not Resolved - **Results in Death**), Carotid artery stenosis (n/a - Unknown - **Results in Death**), Circulatory collapse (n/a - Unknown - **Results in Death**), Ischaemic stroke (26d - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16242 | click or scan EU-EC-10008905646 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Confusional state (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoglobin decreased (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16243 | click or scan EU-EC-10008905642 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Balance disorder (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dizziness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial haematoma (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16244 | click or scan EU-EC-10008905634 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 16245 | click or scan EU-EC-10008905613 | | 2021-06-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dysarthria (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Haemorrhagic stroke (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16246 | click or scan EU-EC-10008904925 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Embolism (n/a - Unknown - **Results in Death**), Pelvic venous thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16247 | click or scan EU-EC-10008904916 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Compartment syndrome (n/a - Unknown - **Results in Death**), Deep vein thrombosis (2d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**), Peripheral swelling (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16248 | click or scan EU-EC-10008904875 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Speech disorder (n/a - Unknown - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Status epilepticus (1d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16249 | click or scan EU-EC-10008904869 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Metabolic acidosis (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16250 | click or scan EU-EC-10008904854 | | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Cardiac ventricular thrombosis (1d - Fatal - **Results in Death**, Life Threatening), Intestinal ischaemia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Mesenteric artery embolism (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 16251 | click or scan EU-EC-10008904831 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Unknown - **Results in Death**), Back pain (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16252 | click or scan EU-EC-10008904412 | | 2021-06-04 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16253 | click or scan EU-EC-10008904411 |  | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Subdural haematoma (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 16254 | click or scan EU-EC-10008904402 |  | 2021-06-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (18d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 16255 | click or scan EU-EC-10008903993 |  | 2021-06-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (n/a - Recovered/Resolved With Sequelae - **Results in Death**), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**), Pneumonia (n/a - Recovered/Resolved With Sequelae - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16256 | click or scan EU-EC-10008903685 |  | 2021-06-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Hepatic vascular thrombosis (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**), Splenic infarction (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16257 | click or scan EU-EC-10008903533 |  | 2021-06-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Pyrexia (n/a - Unknown - **Results in Death**), Status epilepticus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 16258 | click or scan EU-EC-10008903008 |  | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Female | Herpes simplex encephalitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16259 | click or scan EU-EC-10008902140 |  | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (1d - Unknown - ), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16260 | click or scan EU-EC-10008901592 |  | 2021-06-04 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |
| 16261 | click or scan EU-EC-10008901579 |  | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16262 | click or scan EU-EC-10008901574 |  | 2021-06-04 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16263 | click or scan EU-EC-10008901507 | | 2021-06-04 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 16264 | click or scan EU-EC-10008901506 | | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Male | Hepatitis acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 16265 | click or scan EU-EC-10008901500 | | 2021-06-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16266 | click or scan EU-EC-10008901400 | | 2021-06-04 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) |
| 16267 | click or scan EU-EC-10008901288 | | 2021-06-04 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16268 | click or scan EU-EC-10008901284 | | 2021-06-04 | Healthcare Professional | EEA | More than 85 Years | Male | Herpes zoster disseminated (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16269 | click or scan EU-EC-10008901264 | | 2021-06-04 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [DIAZEPAM] (S - Agitation - Not applicable - [n/a - 30[drp] - Oral]), [RISPERIDONE] (S - Paranoia - Not applicable - [n/a - 6mg - Oral]), [TIAPRIDE HYDROCHLORIDE] (S - Paranoia - Not applicable - [n/a - 200mg - Oral]) |
| 16270 | click or scan EU-EC-10008901258 | | 2021-06-04 | Healthcare Professional | EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16271 | click or scan EU-EC-10008899815 | | 2021-06-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (30min - Fatal - **Results in Death**), Cyanosis (30min - Fatal - **Results in Death**), Respiratory distress (30min - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16272 | click or scan EU-EC-10008899139 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16273** | click or scan EU-EC-10008898798 | | 2021-06-04 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16274** | click or scan EU-EC-10008898766 | | 2021-06-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Drowning (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16275** | click or scan EU-EC-10008898604 | | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **16276** | click or scan EU-EC-10008898258 | | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Female | Administration site pain (6d - Fatal - **Results in Death**), Deep vein thrombosis (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Somnolence (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16277** | click or scan EU-EC-10008898246 | | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |
| **16278** | click or scan EU-EC-10008898212 | | 2021-06-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16279** | click or scan EU-EC-10008897652 | | 2021-06-04 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16280** | click or scan EU-EC-10008897625 | | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16281** | click or scan EU-EC-10008897519 | | 2021-06-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (0d - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16282** | click or scan EU-EC-10008897480 | | 2021-06-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16283 | click or scan EU-EC-10008896587 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16284 | click or scan EU-EC-10008896448 | | 2021-06-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 16285 | click or scan EU-EC-10008896443 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebellar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16286 | click or scan EU-EC-10008895703 | | 2021-06-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 16287 | click or scan EU-EC-10008895238 | | 2021-06-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16288 | click or scan EU-EC-10008894410 | | 2021-06-04 | Healthcare Professional | EEA | 18-64 Years | Female | Influenza like illness (n/a - Unknown - ), Petechiae (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16289 | click or scan EU-EC-10008894115 | | 2021-06-04 | Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Blood glucose abnormal (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Eye pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Neuroendocrine carcinoma of the skin (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Varicose ulceration (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 16290 | click or scan EU-EC-10008893330 | | 2021-06-04 | Healthcare Professional | Non EEA | Not Specified | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16291 | click or scan EU-EC-10008893142 | | 2021-06-04 | Non Healthcare Professional | EEA | Not Specified | Male | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16292 | click or scan EU-EC-10008892752 | | 2021-06-04 | Healthcare Professional | EEA | 65-85 Years | Female | Carotid artery thrombosis (n/a - Fatal - **Results in Death**), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebral mass effect (n/a - Fatal - **Results in Death**), Thrombectomy (n/a - Fatal - **Results in Death**), Thrombolysis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16293 | click or scan EU-EC-10008892695 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16294 | click or scan EU-EC-10008892502 | | 2021-06-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal rigidity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal tenderness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral circulatory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16295 | click or scan EU-EC-10008891900 | | 2021-06-04 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebellar haemorrhage (23d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16296 | click or scan EU-EC-10008889412 | | 2021-06-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16297 | click or scan EU-EC-10008889840 | | 2021-06-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 16298 | click or scan EU-EC-10008888822 | | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 16299 | click or scan EU-EC-10008888812 | | 2021-06-03 | Healthcare Professional | EEA | 18-64 Years | Male | Autoimmune haemolytic anaemia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]), [AMOXICILLIN] (S - Tooth infection - Not applicable - [8d - 750mg - Oral]) |
| 16300 | click or scan EU-EC-10008887931 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (1d - Unknown - Other Medically Important Condition), Lethargy (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16301 | click or scan EU-EC-10008887723 | | 2021-06-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - ), Tremor (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16302 | click or scan EU-EC-10008887515 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16303 | click or scan EU-EC-10008887032 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 16304 | click or scan EU-EC-10008886631 | | 2021-06-03 | Healthcare Professional | EEA | 18-64 Years | Male | Coronary artery occlusion (0d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16305 | click or scan EU-EC-10008886490 | | 2021-06-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac tamponade (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16306 | click or scan EU-EC-10008886358 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cyanosis (1d - Fatal - **Results in Death**), Peripheral coldness (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16307 | click or scan EU-EC-10008886295 | | 2021-06-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16308 | click or scan EU-EC-10008886007 | | 2021-06-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Unknown - Life Threatening, Other Medically Important Condition), Cardio-respiratory arrest (1d - Unknown - Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16309 | click or scan EU-EC-10008885946 | | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16310 | click or scan EU-EC-10008885210 | | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16311 | click or scan EU-EC-10008885209 | | 2021-06-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16312** | click or scan EU-EC-10008885193 |  | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **16313** | click or scan EU-EC-10008885189 |  | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **16314** | click or scan EU-EC-10008885167 |  | 2021-06-03 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **16315** | click or scan EU-EC-10008885137 |  | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16316** | click or scan EU-EC-10008885113 |  | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **16317** | click or scan EU-EC-10008885060 |  | 2021-06-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **16318** | click or scan EU-EC-10008885050 |  | 2021-06-03 | Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **16319** | click or scan EU-EC-10008884740 |  | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16320** | click or scan EU-EC-10008884452 |  | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **16321** | click or scan EU-EC-10008884206 |  | 2021-06-03 | Healthcare Professional | Non EEA | Not Specified | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Urinary retention (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16322** | click or scan EU-EC-10008883511 | | 2021-06-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure increased (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16323** | click or scan EU-EC-10008883345 | | 2021-06-03 | Healthcare Professional | EEA | More than 85 Years | Female | Encephalitis brain stem (23d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16324** | click or scan EU-EC-10008882790 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16325** | click or scan EU-EC-10008882165 | | 2021-06-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16326** | click or scan EU-EC-10008881285 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16327** | click or scan EU-EC-10008881247 | | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16328** | click or scan EU-EC-10008881011 | | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**), Hepatic cancer (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **16329** | click or scan EU-EC-10008880308 | | 2021-06-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16330** | click or scan EU-EC-10008879961 | | 2021-06-03 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **16331** | click or scan EU-EC-10008877988 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **16332** | click or scan EU-EC-10008877917 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Bundle branch block left (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Hyperlipidaemia (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16333 | click or scan EU-EC-10008877754 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16334 | click or scan EU-EC-10008877045 | | 2021-06-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Essential hypertension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypercapnia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypercholesterolaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vitamin B12 deficiency (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16335 | click or scan EU-EC-10008875837 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16336 | click or scan EU-EC-10008875680 | | 2021-06-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16337 | click or scan EU-EC-10008875131 | | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Female | Rectal haemorrhage (28d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 16338 | click or scan EU-EC-10008875112 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16339 | click or scan EU-EC-10008874759 | | 2021-06-02 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16340 | click or scan EU-EC-10008874033 | | 2021-06-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16341 | click or scan EU-EC-10008873964 |  | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 16342 | click or scan EU-EC-10008873614 |  | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (5d - Unknown - Life Threatening), Chills (5d - Unknown - Life Threatening), Cold sweat (5d - Unknown - Life Threatening), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (5d - Unknown - Life Threatening), Fatigue (5d - Unknown - Life Threatening), Feeling of body temperature change (5d - Unknown - Life Threatening), Nausea (5d - Unknown - Life Threatening), Pain (5d - Unknown - Life Threatening), Pain in extremity (5d - Unknown - Life Threatening), Pallor (5d - Unknown - Life Threatening), Unresponsive to stimuli (5d - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16343 | click or scan EU-EC-10008873418 |  | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Diabetic ketoacidosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16344 | click or scan EU-EC-10008872894 |  | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16345 | click or scan EU-EC-10008872836 |  | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [23d - 1 {DF} - Intramuscular]) |
| 16346 | click or scan EU-EC-10008872833 |  | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), SARS-CoV-2 antibody test negative (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]) |
| 16347 | click or scan EU-EC-10008872689 |  | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Male | Acute chest syndrome (n/a - Not Recovered/Not Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sickle cell anaemia with crisis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16348 | click or scan EU-EC-10008872676 |  | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16349 | click or scan EU-EC-10008872606 |  | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]) |
| 16350 | click or scan EU-EC-10008872460 |  | 2021-06-02 | Healthcare Professional | EEA | Not Specified | Not Specified | Face oedema (0d - Fatal - **Results in Death**), Foetal death (0d - Fatal - **Results in Death**), High foetal head (0d - Fatal - **Results in Death**), Palatal disorder (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16351** | click or scan EU-EC-10008872455 | | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Male | C-reactive protein increased (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16352** | click or scan EU-EC-10008872413 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Unknown - Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16353** | click or scan EU-EC-10008872049 | | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16354** | click or scan EU-EC-10008872033 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16355** | click or scan EU-EC-10008871903 | | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemolytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jaundice (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16356** | click or scan EU-EC-10008871815 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Recovered/Resolved - ), Chest pain (n/a - Recovered/Resolved - ), Dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral coldness (n/a - Recovered/Resolved - ), Somnolence (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16357** | click or scan EU-EC-10008871216 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (24d - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure to SARS-CoV-2 (24d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16358 | click or scan EU-EC-10008870844 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Alanine aminotransferase increased (n/a - Fatal - **Results in Death**), Albumin globulin ratio normal (n/a - Fatal - **Results in Death**), Anion gap normal (n/a - Fatal - **Results in Death**), Aortic aneurysm (n/a - Fatal - **Results in Death**), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**), Atelectasis (n/a - Fatal - **Results in Death**), Bacterial test positive (n/a - Fatal - **Results in Death**), Base excess negative (n/a - Fatal - **Results in Death**), Basophil count decreased (n/a - Fatal - **Results in Death**), Basophil percentage decreased (n/a - Fatal - **Results in Death**), Bilirubin urine (n/a - Fatal - **Results in Death**), Blood alkaline phosphatase increased (n/a - Fatal - **Results in Death**), Blood bicarbonate normal (n/a - Fatal - **Results in Death**), Blood bilirubin increased (n/a - Fatal - **Results in Death**), Blood calcium decreased (n/a - Fatal - **Results in Death**), Blood chloride increased (n/a - Fatal - **Results in Death**), Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood gases (n/a - Fatal - **Results in Death**), Blood glucose decreased (n/a - Fatal - **Results in Death**), Blood lactic acid (n/a - Fatal - **Results in Death**), Blood magnesium increased (n/a - Fatal - **Results in Death**), Blood pH decreased (n/a - Fatal - **Results in Death**), Blood potassium normal (n/a - Fatal - **Results in Death**), Blood sodium increased (n/a - Fatal - **Results in Death**), Blood urea increased (n/a - Fatal - **Results in Death**), Blood urea nitrogen/creatinine ratio (n/a - Fatal - **Results in Death**), Blood urine present (n/a - Fatal - **Results in Death**), Calcium ionised normal (n/a - Fatal - **Results in Death**), Carbon dioxide decreased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest X-ray abnormal (n/a - Fatal - **Results in Death**), Drooling (n/a - Fatal - **Results in Death**), Electrocardiogram (n/a - Fatal - **Results in Death**), Electroencephalogram abnormal (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Fatal - **Results in Death**), Endotracheal intubation (n/a - Fatal - **Results in Death**), Eosinophil count normal (n/a - Fatal - **Results in Death**), Eosinophil percentage (n/a - Fatal - **Results in Death**), Flatulence (n/a - Fatal - **Results in Death**), Full blood count (n/a - Fatal - **Results in Death**), Globulins increased (n/a - Fatal - **Results in Death**), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**), Glucose urine absent (n/a - Fatal - **Results in Death**), Granulocyte percentage (n/a - Fatal - **Results in Death**), Haematocrit decreased (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**), Imaging procedure artifact (n/a - Fatal - **Results in Death**), Immature granulocyte count (n/a - Fatal - **Results in Death**), Influenza A virus test negative (n/a - Fatal - **Results in Death**), Influenza B virus test (n/a - Fatal - **Results in Death**), Lymphocyte count normal (n/a - Fatal - **Results in Death**), Lymphocyte percentage decreased (n/a - Fatal - **Results in Death**), Mean cell haemoglobin concentration decreased (n/a - Fatal - **Results in Death**), Mean cell haemoglobin normal (n/a - Fatal - **Results in Death**), Mean cell volume increased (n/a - Fatal - **Results in Death**), Mean platelet volume increased (n/a - Fatal - **Results in Death**), Metabolic function test (n/a - Fatal - **Results in Death**), Monocyte count normal (n/a - Fatal - **Results in Death**), Monocyte percentage (n/a - Fatal - **Results in Death**), Neutrophil count normal (n/a - Fatal - **Results in Death**)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16359 | click or scan EU-EC-10008870622 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16360 | click or scan EU-EC-10008870444 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**), Respiratory acidosis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 16361 | click or scan EU-EC-10008870405 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cold sweat (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16362 | click or scan EU-EC-10008870043 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16363 | click or scan EU-EC-10008870040 |  | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16364 | click or scan EU-EC-10008870015 |  | 2021-06-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16365 | click or scan EU-EC-10008869563 |  | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anxiety (16d - Unknown - Caused/Prolonged Hospitalisation), Asthenia (16d - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (16d - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (16d - Unknown - Caused/Prolonged Hospitalisation), Constipation (16d - Unknown - Caused/Prolonged Hospitalisation), Cough (16d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysuria (16d - Unknown - Caused/Prolonged Hospitalisation), Malaise (16d - Unknown - Caused/Prolonged Hospitalisation), Metabolic acidosis (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory alkalosis (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary incontinence (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary retention (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16366 | click or scan EU-EC-10008869045 |  | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16367 | click or scan EU-EC-10008868664 |  | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 16368 | click or scan EU-EC-10008868063 |  | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16369 | click or scan EU-EC-10008868036 |  | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Magnetic resonance imaging abnormal (n/a - Fatal - **Results in Death**), Spinal X-ray abnormal (n/a - Fatal - **Results in Death**), Spinal compression fracture (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 16370 | click or scan EU-EC-10008867814 |  | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (1d - Fatal - **Results in Death**), Back pain (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16371 | click or scan EU-EC-10008867667 |  | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16372** | click or scan EU-EC-10008867481 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Neurological symptom (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16373** | click or scan EU-EC-10008867430 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16374** | click or scan EU-EC-10008867429 | | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16375** | click or scan EU-EC-10008867421 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coronary artery embolism (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic vascular thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracardiac thrombus (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal vascular thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| **16376** | click or scan EU-EC-10008867334 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16377** | click or scan EU-EC-10008867147 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic aneurysm rupture (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16378** | click or scan EU-EC-10008867145 | | 2021-06-02 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16379** | click or scan EU-EC-10008867141 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vertebral artery aneurysm (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **16380** | click or scan EU-EC-10008866719 | | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16381** | click or scan EU-EC-10008866619 | | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16382** | click or scan EU-EC-10008866618 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16383** | click or scan EU-EC-10008866612 | | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16384** | click or scan EU-EC-10008866609 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16385** | click or scan EU-EC-10008866598 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16386** | click or scan EU-EC-10008866537 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16387** | click or scan EU-EC-10008866536 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chronic obstructive pulmonary disease (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Femoral neck fracture (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fracture displacement (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Head injury (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16388** | click or scan EU-EC-10008866497 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aspiration (54d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16389** | click or scan EU-EC-10008866195 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Body temperature increased (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16390** | click or scan EU-EC-10008866104 | | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Male | Diffuse alveolar damage (n/a - Not Recovered/Not Resolved - Life Threatening), Organising pneumonia (15d - Fatal - **Results in Death**), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening), Thrombophlebitis (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16391** | click or scan EU-EC-10008866066 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16392** | click or scan EU-EC-10008866056 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| **16393** | click or scan EU-EC-10008866028 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (14d - Fatal - **Results in Death**, Other Medically Important Condition), Metabolic encephalopathy (14d - Fatal - **Results in Death**, Other Medically Important Condition), Organ failure (14d - Fatal - **Results in Death**), Pneumonia (14d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (14d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16394** | click or scan EU-EC-10008865689 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Unknown]) |
| **16395** | click or scan EU-EC-10008865365 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16396** | click or scan EU-EC-10008865334 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16397** | click or scan EU-EC-10008865326 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16398** | click or scan EU-EC-10008865317 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16399** | click or scan EU-EC-10008865239 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16400** | click or scan EU-EC-10008865222 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16401** | click or scan EU-EC-10008865188 | | 2021-06-02 | Non Healthcare Professional | Non EEA | Not Specified | Female | Heart rate increased (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16402** | click or scan EU-EC-10008865183 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16403** | click or scan EU-EC-10008864974 | | 2021-06-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16404** | click or scan EU-EC-10008864968 | | 2021-06-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16405** | click or scan EU-EC-10008864927 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (2d - Fatal - **Results in Death**), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Sensation of foreign body (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16406** | click or scan EU-EC-10008864899 | | 2021-06-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epistaxis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16407** | click or scan EU-EC-10008864888 | | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Female | Shock (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **16408** | click or scan EU-EC-10008864857 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure like phenomena (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16409** | click or scan EU-EC-10008864777 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16410** | click or scan EU-EC-10008864742 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Disability (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16411** | click or scan EU-EC-10008864725 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (6d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16412** | click or scan EU-EC-10008864622 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16413 | click or scan EU-EC-10008864603 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Irritability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16414 | click or scan EU-EC-10008864553 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 16415 | click or scan EU-EC-10008864400 | | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Arteriospasm coronary (n/a - Unknown - Other Medically Important Condition), Cerebral ischaemia (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16416 | click or scan EU-EC-10008864182 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Coronary artery disease (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16417 | click or scan EU-EC-10008863961 | | 2021-06-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Disseminated Bacillus Calmette-Guerin infection (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 16418 | click or scan EU-EC-10008863907 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16419 | click or scan EU-EC-10008863678 | | 2021-06-02 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Congenital anomaly (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| 16420 | click or scan EU-EC-10008863581 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 16421 | click or scan EU-EC-10008863539 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16422 | click or scan EU-EC-10008863443 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Asymptomatic COVID-19 (21d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16423** | click or scan EU-EC-10008863095 | | 2021-06-02 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperpyrexia (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **16424** | click or scan EU-EC-10008862907 | | 2021-06-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (12d - Fatal - **Results in Death**, Other Medically Important Condition), Atypical pneumonia (12d - Fatal - **Results in Death**, Other Medically Important Condition), Plasma cell myeloma (12d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16425** | click or scan EU-EC-10008862871 | | 2021-06-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16426** | click or scan EU-EC-10008860938 | | 2021-06-02 | Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Vaccination site joint discomfort (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| **16427** | click or scan EU-EC-10008860818 | | 2021-06-02 | Healthcare Professional | EEA | 18-64 Years | Female | Thrombosis (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - n/a]) |
| **16428** | click or scan EU-EC-10008862860 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16429** | click or scan EU-EC-10008862771 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apnoeic attack (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16430** | click or scan EU-EC-10008862670 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16431** | click or scan EU-EC-10008862607 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16432** | click or scan EU-EC-10008862577 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16433** | click or scan EU-EC-10008862550 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Communication disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16434** | click or scan EU-EC-10008862533 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16435** | click or scan EU-EC-10008862251 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16436** | click or scan EU-EC-10008862232 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16437** | click or scan EU-EC-10008862132 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16438** | click or scan EU-EC-10008861725 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypertensive cardiomyopathy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16439** | click or scan EU-EC-10008861659 | | 2021-06-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16440** | click or scan EU-EC-10008861631 | | 2021-06-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16441** | click or scan EU-EC-10008861476 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Laryngeal oedema (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **16442** | click or scan EU-EC-10008861466 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (4d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16443** | click or scan EU-EC-10008861055 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **16444** | click or scan EU-EC-10008860613 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Unknown - ), Purpura (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16445** | click or scan EU-EC-10008860466 | | 2021-06-01 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Headache (n/a - Unknown - ), Muscle spasms (n/a - Unknown - ), Tremor (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16446** | click or scan EU-EC-10008859858 | | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16447** | click or scan EU-EC-10008859383 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cheyne-Stokes respiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16448** | click or scan EU-EC-10008859057 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constipation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infusion site infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Klebsiella infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Transaminases increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16449** | click or scan EU-EC-10008859037 | | 2021-06-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16450** | click or scan EU-EC-10008858955 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16451** | click or scan EU-EC-10008858715 | | 2021-06-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mental impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16452** | click or scan EU-EC-10008858518 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (27d - Fatal - **Results in Death**, Other Medically Important Condition), Chills (27d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Influenza like illness (27d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16453 | click or scan EU-EC-10008858428 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), ELIQUIS [APIXABAN] (S - Embolism - n/a - [n/a - n/a - Oral]) |
| 16454 | click or scan EU-EC-10008857411 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Male | Neurological symptom (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16455 | click or scan EU-EC-10008857392 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16456 | click or scan EU-EC-10008857376 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (5min - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16457 | click or scan EU-EC-10008857354 | | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16458 | click or scan EU-EC-10008857353 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16459 | click or scan EU-EC-10008857312 | | 2021-06-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16460 | click or scan EU-EC-10008857298 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 16461 | click or scan EU-EC-10008857294 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain upper (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Nausea (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (2d - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 16462 | click or scan EU-EC-10008857265 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16463 | click or scan EU-EC-10008857263 |  | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| 16464 | click or scan EU-EC-10008857246 |  | 2021-06-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 16465 | click or scan EU-EC-10008857242 |  | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 16466 | click or scan EU-EC-10008857045 |  | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Female | Bed rest (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), [FENTANYL] (S - Pain - Dose not changed - [n/a - 25ug - n/a]) |
| 16467 | click or scan EU-EC-10008856993 |  | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16468 | click or scan EU-EC-10008856989 |  | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16469 | click or scan EU-EC-10008856953 |  | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16470 | click or scan EU-EC-10008856947 |  | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**), Deep vein thrombosis (0d - Fatal - **Results in Death**), Thrombocytopenia (0d - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16471 | click or scan EU-EC-10008856833 |  | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Lethargy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 16472 | click or scan EU-EC-10008856786 |  | 2021-06-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16473** | click or scan EU-EC-10008856772 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronavirus test positive (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| **16474** | click or scan EU-EC-10008856583 | | 2021-06-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16475** | click or scan EU-EC-10008856275 | | 2021-06-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - ), Haemorrhage (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Impaired driving ability (n/a - Not Recovered/Not Resolved - ), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - ), Urinary incontinence (n/a - Not Recovered/Not Resolved - ), Vaccination complication (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16476** | click or scan EU-EC-10008856011 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Depression (n/a - Unknown - ), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gingival pain (n/a - Unknown - ), Hypotension (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **16477** | click or scan EU-EC-10008855997 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16478** | click or scan EU-EC-10008855993 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16479** | click or scan EU-EC-10008855991 | | 2021-06-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chest discomfort (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **16480** | click or scan EU-EC-10008855987 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16481** | click or scan EU-EC-10008855979 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16482** | click or scan EU-EC-10008855968 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16483** | click or scan EU-EC-10008855964 | | 2021-06-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Oedema peripheral (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **16484** | click or scan EU-EC-10008855958 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16485** | click or scan EU-EC-10008855678 | | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16486** | click or scan EU-EC-10008855592 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary infarction (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16487** | click or scan EU-EC-10008855510 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Female | Chest discomfort (24d - Fatal - **Results in Death**), Dyspnoea (24d - Fatal - **Results in Death**), Grunting (24d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **16488** | click or scan EU-EC-10008855303 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Male | Apraxia (n/a - Fatal - **Results in Death**), Bradyarrhythmia (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**), Disturbance in attention (n/a - Fatal - **Results in Death**), Haemorrhage intracranial (2d - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Intracranial pressure increased (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pupils unequal (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Tonic convulsion (n/a - Fatal - **Results in Death**), Vasoplegia syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16489** | click or scan EU-EC-10008854811 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16490** | click or scan EU-EC-10008854698 | | 2021-06-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Irritability (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16491** | click or scan EU-EC-10008854058 | | 2021-06-01 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16492** | click or scan EU-EC-10008854050 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16493** | click or scan EU-EC-10008853936 | | 2021-06-01 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cough (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16494** | click or scan EU-EC-10008853696 | | 2021-06-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Dysphagia (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling), Hemiparesis (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling), Speech disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling), Urinary hesitation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **16495** | click or scan EU-EC-10008853597 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16496** | click or scan EU-EC-10008853235 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hyperhidrosis (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16497** | click or scan EU-EC-10008853215 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Traumatic intracranial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16498** | click or scan EU-EC-10008853201 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16499** | click or scan EU-EC-10008853190 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**), Abdominal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16500** | click or scan EU-EC-10008853066 | | 2021-06-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16501** | click or scan EU-EC-10008852955 | | 2021-06-01 | Non Healthcare Professional | EEA | Not Specified | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), Blood urine present (n/a - Fatal - **Results in Death**, Life Threatening), Coordination abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gait disturbance (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Hepatic haemorrhage (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16502** | click or scan EU-EC-10008852582 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16503 | click or scan EU-EC-10008851950 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myalgia (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16504 | click or scan EU-EC-10008851151 | | 2021-06-01 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16505 | click or scan EU-EC-10008851132 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16506 | click or scan EU-EC-10008851085 | | 2021-06-01 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16507 | click or scan EU-EC-10008851083 | | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (27d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16508 | click or scan EU-EC-10008851025 | | 2021-06-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16509 | click or scan EU-EC-10008850675 | | 2021-06-01 | Healthcare Professional | EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic valve stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood pressure immeasurable (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchospasm (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Unknown - ), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulse absent (n/a - Unknown - Caused/Prolonged Hospitalisation), Restlessness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Throat tightness (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 16510 | click or scan EU-EC-10008850626 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16511 | click or scan EU-EC-10008850503 | | 2021-06-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal rigidity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal tenderness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral circulatory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16512 | click or scan EU-EC-10008850420 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 16513 | click or scan EU-EC-10008850354 | | 2021-06-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Flushing (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16514 | click or scan EU-EC-10008848857 | | 2021-05-31 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16515 | click or scan EU-EC-10008848664 | | 2021-05-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16516 | click or scan EU-EC-10008848642 | | 2021-05-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16517 | click or scan EU-EC-10008848637 | | 2021-05-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16518 | click or scan EU-EC-10008848410 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Female | Aspiration (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 16519 | click or scan EU-EC-10008848164 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Hyperhidrosis (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16520 | click or scan EU-EC-10008848146 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Female | Aortic thrombosis (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid artery thrombosis (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 16521 | click or scan EU-EC-10008847977 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16522 | click or scan EU-EC-10008847929 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16523 | click or scan EU-EC-10008847837 | | 2021-05-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16524 | click or scan EU-EC-10008847721 | | 2021-05-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Abdominal pain (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Gastrooesophageal reflux disease (n/a - Unknown - ), Headache (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Paraesthesia (n/a - Unknown - ), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [ADENOSINE, SORBITOL (E420), L-METHIONINE ([11C]METHYL)] (I - n/a - n/a - [n/a - n/a - n/a]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (I - n/a - n/a - [n/a - n/a - n/a]), [DIMENHYDRINATE] (I - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE SODIUM] (I - n/a - n/a - [n/a - n/a - n/a]) |
| 16525 | click or scan EU-EC-10008847477 | | 2021-05-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 16526 | click or scan EU-EC-10008847399 | | 2021-05-31 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 16527 | click or scan EU-EC-10008846941 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachyarrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 16528 | click or scan EU-EC-10008846822 | | 2021-05-31 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16529 | click or scan EU-EC-10008846746 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16530 | click or scan EU-EC-10008846160 | | 2021-05-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16531 | click or scan EU-EC-10008846009 | | 2021-05-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 16532 | click or scan EU-EC-10008845688 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16533 | click or scan EU-EC-10008845599 | | 2021-05-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16534 | click or scan EU-EC-10008844978 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16535 | click or scan EU-EC-10008844955 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16536 | click or scan EU-EC-10008844908 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16537 | click or scan EU-EC-10008844842 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombophlebitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 16538 | click or scan EU-EC-10008844829 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16539 | click or scan EU-EC-10008844827 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16540 | click or scan EU-EC-10008844806 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16541 | click or scan EU-EC-10008844783 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16542 | click or scan EU-EC-10008844770 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (12d - Fatal - **Results in Death**), Feeling abnormal (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 16543 | click or scan EU-EC-10008844768 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 16544 | click or scan EU-EC-10008844720 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 16545 | click or scan EU-EC-10008844709 | | 2021-05-31 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16546 | click or scan EU-EC-10008844704 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| 16547 | click or scan EU-EC-10008844685 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Drug withdrawn - [31d - 1{DF} - Intramuscular]) |
| 16548 | click or scan EU-EC-10008844654 | | 2021-05-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 16549 | click or scan EU-EC-10008844652 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16550 | click or scan EU-EC-10008844644 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular]) |
| 16551 | click or scan EU-EC-10008844637 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16552 | click or scan EU-EC-10008844635 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Male | Pleural effusion (n/a - Fatal - **Results in Death**), Respiratory acidosis (1wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 16553 | click or scan EU-EC-10008844631 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16554 | click or scan EU-EC-10008844627 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| 16555 | click or scan EU-EC-10008844549 | | 2021-05-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ), Pneumothorax (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16556 | click or scan EU-EC-10008843578 | | 2021-05-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16557 | click or scan EU-EC-10008843483 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16558 | click or scan EU-EC-10008843341 | | 2021-05-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (31d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal inflammation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Muscle atrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 16559 | click or scan EU-EC-10008843212 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Cholestasis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemolysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatorenal syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperbilirubinaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Jaundice (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16560 | click or scan EU-EC-10008842815 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [NOT AVAILABLE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16561 | click or scan EU-EC-10008842596 | | 2021-05-31 | Non Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Brachiocephalic artery stenosis (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Carotid artery stenosis (n/a - Fatal - **Results in Death**), Coma scale abnormal (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), International normalised ratio decreased (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Thrombectomy (n/a - Fatal - **Results in Death**), Vertebral artery stenosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 16562 | click or scan EU-EC-10008842471 | | 2021-05-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16563 | click or scan EU-EC-10008842404 | | 2021-05-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16564 | click or scan EU-EC-10008842395 | | 2021-05-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16565 | click or scan EU-EC-10008842223 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16566 | click or scan EU-EC-10008841503 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16567 | click or scan EU-EC-10008841207 | | 2021-05-31 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral infarction (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16568 | click or scan EU-EC-10008840755 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16569 | click or scan EU-EC-10008840753 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Bronchitis (n/a - Fatal - **Results in Death**), Fungal infection (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16570 | click or scan EU-EC-10008840740 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - n/a]) |
| 16571 | click or scan EU-EC-10008840737 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Male | Hypersensitivity (n/a - Fatal - **Results in Death**), Laryngeal oedema (n/a - Fatal - **Results in Death**), Oral mucosal exfoliation (n/a - Fatal - **Results in Death**), Pharyngeal swelling (n/a - Fatal - **Results in Death**), Swollen tongue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16572 | click or scan EU-EC-10008840736 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16573 | click or scan EU-EC-10008840477 | | 2021-05-31 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16574 | click or scan EU-EC-10008840271 | | 2021-05-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16575 | click or scan EU-EC-10008840059 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16576 | click or scan EU-EC-10008839971 | | 2021-05-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16577 | click or scan EU-EC-10008839783 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16578 | click or scan EU-EC-10008839620 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**), Aphasia (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 16579 | click or scan EU-EC-10008839078 | | 2021-05-31 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (3d - Fatal - **Results in Death**), Respiratory failure (3d - Fatal - **Results in Death**), SARS-CoV-2 test positive (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16580 | click or scan EU-EC-10008838993 | | 2021-05-31 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16581 | click or scan EU-EC-10008838511 | | 2021-05-31 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16582 | click or scan EU-EC-10008838412 | | 2021-05-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16583 | click or scan EU-EC-10008836909 | | 2021-05-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16584 | click or scan EU-EC-10008834817 | | 2021-05-30 | Non Healthcare Professional | EEA | Not Specified | Female | Embolism arterial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolism venous (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 16585 | click or scan EU-EC-10008834778 | | 2021-05-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16586 | click or scan EU-EC-10008832254 | | 2021-05-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial ischaemia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16587 | click or scan EU-EC-10008832241 | | 2021-05-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - **Results in Death**, Life Threatening), Back pain (n/a - Unknown - **Results in Death**, Life Threatening), Candida infection (n/a - Unknown - **Results in Death**, Life Threatening), Deep vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening), Feeling abnormal (n/a - Unknown - **Results in Death**, Life Threatening), Infection (n/a - Unknown - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 16588 | click or scan EU-EC-10008832237 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Recovered/Resolved - **Results in Death**), Cerebral infarction (n/a - Recovered/Resolved - **Results in Death**), Dyspnoea (n/a - Recovered/Resolved - **Results in Death**), Embolism venous (n/a - Fatal - **Results in Death**), Hypotension (n/a - Recovered/Resolved - **Results in Death**), Hypoxia (n/a - Recovered/Resolved - **Results in Death**), Pulmonary embolism (n/a - Recovered/Resolved - **Results in Death**), Tachycardia (n/a - Recovered/Resolved - **Results in Death**), Thrombolysis (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 16589 | click or scan EU-EC-10008831985 | | 2021-05-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16590** | click or scan EU-EC-10008831127 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16591** | click or scan EU-EC-10008831109 | | 2021-05-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial strain imaging (n/a - Unknown - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16592** | click or scan EU-EC-10008831104 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16593** | click or scan EU-EC-10008830671 | | 2021-05-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arterial thrombosis (n/a - Unknown - **Results in Death**), Cerebral haemorrhage (n/a - Unknown - **Results in Death**), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - **Results in Death**), Pancytopenia (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), White blood cell count increased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16594** | click or scan EU-EC-10008830331 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Petechiae (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16595** | click or scan EU-EC-10008830300 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16596** | click or scan EU-EC-10008830286 | | 2021-05-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Metastases to lung (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16597** | click or scan EU-EC-10008829706 | | 2021-05-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16598** | click or scan EU-EC-10008829350 | | 2021-05-29 | Healthcare Professional | Non EEA | Not Specified | Male | Aspiration (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Device related infection (12d - Not Recovered/Not Resolved - **Results in Death**), Lower respiratory tract infection (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16599** | click or scan EU-EC-10008829317 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aneurysm ruptured (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Syncope (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16600** | click or scan EU-EC-10008829023 | | 2021-05-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Cardiac arrest (n/a - Unknown - **Results in Death**), Cardiogenic shock (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Unknown - **Results in Death**), Pericardial effusion (n/a - Unknown - **Results in Death**), Peripheral ischaemia (n/a - Unknown - **Results in Death**), Pulmonary oedema (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16601** | click or scan EU-EC-10008828676 | | 2021-05-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **16602** | click or scan EU-EC-10008828608 | | 2021-05-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (60d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16603** | click or scan EU-EC-10008828583 | | 2021-05-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atelectasis (n/a - Unknown - **Results in Death**), Cardiac failure congestive (12d - Fatal - **Results in Death**), Cardiomegaly (n/a - Unknown - **Results in Death**), Chromaturia (n/a - Unknown - **Results in Death**), Local reaction (n/a - Unknown - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**), Oedema peripheral (n/a - Unknown - **Results in Death**), Pleural effusion (n/a - Unknown - **Results in Death**), Rash (n/a - Unknown - **Results in Death**), Respiratory rate increased (n/a - Unknown - **Results in Death**), Wheezing (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **16604** | click or scan EU-EC-10008828573 | | 2021-05-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Unknown - **Results in Death**), Aphasia (n/a - Unknown - **Results in Death**), Cerebrovascular accident (38d - Fatal - **Results in Death**), Circulatory collapse (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Facial paralysis (n/a - Unknown - **Results in Death**), Hemianopia (n/a - Unknown - **Results in Death**), Hemiparesis (n/a - Unknown - **Results in Death**), Hypertension (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**), Pain (n/a - Unknown - **Results in Death**), Pneumonia aspiration (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Restlessness (n/a - Unknown - **Results in Death**), Secretion discharge (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **16605** | click or scan EU-EC-10008828572 | | 2021-05-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16606** | click or scan EU-EC-10008827370 | | 2021-05-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **16607** | click or scan EU-EC-10008826671 | | 2021-05-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Unknown - **Results in Death**), Feeling cold (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16608** | click or scan EU-EC-10008826615 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Carotid artery occlusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic transformation stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercoagulation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16609** | click or scan EU-EC-10008826608 | | 2021-05-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute cardiac event (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| **16610** | click or scan EU-EC-10008826563 | | 2021-05-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral infarction (4d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **16611** | click or scan EU-EC-10008826541 | | 2021-05-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic occlusion (n/a - Not Recovered/Not Resolved - **Results in Death**), Aortic thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Restlessness (n/a - Unknown - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16612** | click or scan EU-EC-10008826068 | | 2021-05-29 | Healthcare Professional | EEA | 65-85 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16613** | click or scan EU-EC-10008825993 | | 2021-05-29 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16614** | click or scan EU-EC-10008825644 | | 2021-05-29 | Healthcare Professional | EEA | More than 85 Years | Female | Acute pulmonary oedema (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **16615** | click or scan EU-EC-10008824882 | | 2021-05-29 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **16616** | click or scan EU-EC-10008824752 | | 2021-05-29 | Healthcare Professional | EEA | More than 85 Years | Female | Disorientation (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **16617** | click or scan EU-EC-10008824484 | | 2021-05-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Application site pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **16618** | click or scan EU-EC-10008824362 | | 2021-05-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16619 | click or scan EU-EC-10008823398 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 16620 | click or scan EU-EC-10008823301 | | 2021-05-28 | Healthcare Professional | EEA | 18-64 Years | Male | Vertebrobasilar stroke (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) |
| 16621 | click or scan EU-EC-10008823249 | | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Lung infiltration (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16622 | click or scan EU-EC-10008823047 | | 2021-05-28 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |
| 16623 | click or scan EU-EC-10008822615 | | 2021-05-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16624 | click or scan EU-EC-10008822405 | | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (1d - Unknown - Other Medically Important Condition), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (1d - Unknown - ), Hypotension (1d - Unknown - ), Presyncope (1d - Unknown - ), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 16625 | click or scan EU-EC-10008820943 | | 2021-05-28 | Healthcare Professional | EEA | 18-64 Years | Female | Atrial fibrillation (2d - Fatal - **Results in Death**), Back pain (5d - Fatal - **Results in Death**), Cardiovascular disorder (2d - Fatal - **Results in Death**), Dyspnoea (5d - Fatal - **Results in Death**), Hyperlactacidaemia (5d - Fatal - **Results in Death**), Metabolic acidosis (2d - Fatal - **Results in Death**), Pain (2d - Fatal - **Results in Death**), Pericardial effusion (2d - Fatal - **Results in Death**), Pleural effusion (2d - Fatal - **Results in Death**), Polycythaemia (2d - Fatal - **Results in Death**), Systemic inflammatory response syndrome (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16626 | click or scan EU-EC-10008820868 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypertensive crisis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16627 | click or scan EU-EC-10008820858 | | 2021-05-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16628 | click or scan EU-EC-10008820461 | | 2021-05-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16629 | click or scan EU-EC-10008820316 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16630 | click or scan EU-EC-10008820174 |  | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16631 | click or scan EU-EC-10008820147 |  | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Vaccination site reaction (n/a - Unknown - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16632 | click or scan EU-EC-10008820091 |  | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16633 | click or scan EU-EC-10008820031 |  | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16634 | click or scan EU-EC-10008820011 |  | 2021-05-28 | Healthcare Professional | EEA | More than 85 Years | Male | Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| 16635 | click or scan EU-EC-10008819935 |  | 2021-05-28 | Healthcare Professional | EEA | Not Specified | Male | Foetal death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 16636 | click or scan EU-EC-10008819893 |  | 2021-05-28 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - .3mL - Intramuscular]) |
| 16637 | click or scan EU-EC-10008819889 |  | 2021-05-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (5d - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 16638 | click or scan EU-EC-10008819839 |  | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16639 | click or scan EU-EC-10008819740 |  | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 16640 | click or scan EU-EC-10008819685 |  | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16641** | click or scan EU-EC-10008819667 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Agitation (10d - Fatal - **Results in Death**), Altered state of consciousness (10d - Fatal - **Results in Death**), Axillary vein thrombosis (10d - Fatal - **Results in Death**), Brain abscess (10d - Fatal - **Results in Death**), Brain empyema (10d - Fatal - **Results in Death**), Cavernous sinus thrombosis (10d - Fatal - **Results in Death**), Coagulopathy (10d - Fatal - **Results in Death**), Confusional state (10d - Fatal - **Results in Death**), Conjunctivitis (10d - Fatal - **Results in Death**), Death (10d - Fatal - **Results in Death**), Delirium (10d - Fatal - **Results in Death**), Erythema (10d - Fatal - **Results in Death**), Eye oedema (10d - Fatal - **Results in Death**), Hypersensitivity (10d - Fatal - **Results in Death**), Jugular vein thrombosis (10d - Fatal - **Results in Death**), Meningitis bacterial (10d - Fatal - **Results in Death**), Nervous system disorder (10d - Fatal - **Results in Death**), Sinusitis (10d - Fatal - **Results in Death**), Subclavian vein thrombosis (10d - Fatal - **Results in Death**), Transverse sinus thrombosis (10d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16642** | click or scan EU-EC-10008819666 | | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (16d - Fatal - **Results in Death**), General physical health deterioration (16d - Fatal - **Results in Death**), Malaise (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16643** | click or scan EU-EC-10008819559 | | 2021-05-28 | Healthcare Professional | EEA | Not Specified | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16644** | click or scan EU-EC-10008819497 | | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16645** | click or scan EU-EC-10008819303 | | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16646** | click or scan EU-EC-10008819233 | | 2021-05-28 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16647** | click or scan EU-EC-10008819117 | | 2021-05-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Brain stem stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16648** | click or scan EU-EC-10008819107 | | 2021-05-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **16649** | click or scan EU-EC-10008818940 | | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Oedema peripheral (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16650** | click or scan EU-EC-10008818736 | | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute aortic syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Wrong product administered (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16651** | click or scan EU-EC-10008818736 | | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute aortic syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Wrong product administered (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16652** | click or scan EU-EC-10008818101 | | 2021-05-28 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Small intestinal haemorrhage (n/a - Fatal - **Results in Death**), Splenic infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16653** | click or scan EU-EC-10008818058 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suspected COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16654** | click or scan EU-EC-10008817905 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16655** | click or scan EU-EC-10008817886 | | 2021-05-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Food refusal (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16656** | click or scan EU-EC-10008817772 | | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16657** | click or scan EU-EC-10008817457 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac tamponade (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16658** | click or scan EU-EC-10008817429 | | 2021-05-28 | Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16659** | click or scan EU-EC-10008817086 | | 2021-05-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16660** | click or scan EU-EC-10008816756 | | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16661** | click or scan EU-EC-10008816714 |  | 2021-05-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16662** | click or scan EU-EC-10008816490 |  | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - ), Tremor (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **16663** | click or scan EU-EC-10008816357 |  | 2021-05-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **16664** | click or scan EU-EC-10008816153 |  | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16665** | click or scan EU-EC-10008816124 |  | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Disabling), Pyrexia (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16666** | click or scan EU-EC-10008816091 |  | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erysipelas (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic acidosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16667** | click or scan EU-EC-10008815480 |  | 2021-05-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16668** | click or scan EU-EC-10008815343 |  | 2021-05-28 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Leukopenia (20d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16669** | click or scan EU-EC-10008815335 |  | 2021-05-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16670 | click or scan EU-EC-10008815281 | | 2021-05-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Recovered/Resolved - ), Dysphagia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Malaise (n/a - Recovered/Resolved - ), Pupillary reflex impaired (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Somnolence (n/a - Fatal - **Results in Death**), Somnolence (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16671 | click or scan EU-EC-10008815219 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16672 | click or scan EU-EC-10008815107 | | 2021-05-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebral cyst (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16673 | click or scan EU-EC-10008815095 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16674 | click or scan EU-EC-10008814949 | | 2021-05-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16675 | click or scan EU-EC-10008814937 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16676 | click or scan EU-EC-10008814925 | | 2021-05-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16677 | click or scan EU-EC-10008814845 | | 2021-05-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16678 | click or scan EU-EC-10008814255 | | 2021-05-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hangover (n/a - Unknown - ), Headache (n/a - Unknown - ), Inflammation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - ), Pericardial disease (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16679 | click or scan EU-EC-10008813734 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Unknown - Other Medically Important Condition), Blood pressure fluctuation (n/a - Unknown - ), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 16680 | click or scan EU-EC-10008813371 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 16681 | click or scan EU-EC-10008813343 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16682 | click or scan EU-EC-10008813112 | | 2021-05-28 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16683 | click or scan EU-EC-10008813076 | | 2021-05-28 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16684 | click or scan EU-EC-10008812590 | | 2021-05-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16685 | click or scan EU-EC-10008812253 | | 2021-05-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16686 | click or scan EU-EC-10008811593 | | 2021-05-28 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (0d - Fatal - **Results in Death**), Vaccination failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 16687 | click or scan EU-EC-10008810706 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | COVID-19 (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16688 | click or scan EU-EC-10008810624 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16689** | click or scan EU-EC-10008810382 | | 2021-05-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16690** | click or scan EU-EC-10008810063 | | 2021-05-27 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16691** | click or scan EU-EC-10008809289 | | 2021-05-27 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **16692** | click or scan EU-EC-10008809234 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Female | Discomfort (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematochezia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemodynamic instability (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Melaena (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16693** | click or scan EU-EC-10008809074 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal wall haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16694** | click or scan EU-EC-10008808808 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery disease (1d - Unknown - Other Medically Important Condition), Cough (1d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16695** | click or scan EU-EC-10008808761 | | 2021-05-27 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16696** | click or scan EU-EC-10008808727 | | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16697** | click or scan EU-EC-10008808626 |  | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16698** | click or scan EU-EC-10008808596 |  | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16699** | click or scan EU-EC-10008808418 |  | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16700** | click or scan EU-EC-10008808315 |  | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea exertional (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Painful respiration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16701** | click or scan EU-EC-10008808300 |  | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| **16702** | click or scan EU-EC-10008808299 |  | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16703** | click or scan EU-EC-10008808173 |  | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Male | Pemphigoid (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **16704** | click or scan EU-EC-10008808167 |  | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **16705** | click or scan EU-EC-10008808154 |  | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 1 {DF} - Intramuscular]) |
| **16706** | click or scan EU-EC-10008808119 |  | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16707 | click or scan EU-EC-10008808118 | | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 16708 | click or scan EU-EC-10008808107 | | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperthermia (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16709 | click or scan EU-EC-10008808026 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary fibrosis (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16710 | click or scan EU-EC-10008807891 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 16711 | click or scan EU-EC-10008807890 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16712 | click or scan EU-EC-10008807794 | | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**), Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 16713 | click or scan EU-EC-10008807422 | | 2021-05-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16714 | click or scan EU-EC-10008806807 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16715 | click or scan EU-EC-10008806530 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Communication disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16716** | click or scan EU-EC-10008806513 | | 2021-05-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16717** | click or scan EU-EC-10008806472 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Death (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16718** | click or scan EU-EC-10008806469 | | 2021-05-27 | Non Healthcare Professional | EEA | More than 85 Years | Female | Ataxia (n/a - Fatal - **Results in Death**), Auditory disorder (n/a - Not Recovered/Not Resolved - ), Disorientation (n/a - Not Recovered/Not Resolved - ), Dysphagia (n/a - Not Recovered/Not Resolved - ), Paralysis (n/a - Not Recovered/Not Resolved - ), Visual impairment (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16719** | click or scan EU-EC-10008806454 | | 2021-05-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Influenza like illness (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16720** | click or scan EU-EC-10008806453 | | 2021-05-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - ), Pancytopenia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16721** | click or scan EU-EC-10008806408 | | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16722** | click or scan EU-EC-10008806277 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16723** | click or scan EU-EC-10008806106 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16724** | click or scan EU-EC-10008805792 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16725** | click or scan EU-EC-10008805717 | | 2021-05-27 | Healthcare Professional | EEA | 18-64 Years | Male | Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16726** | click or scan EU-EC-10008805714 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Back pain (1d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16727** | click or scan EU-EC-10008805639 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **16728** | click or scan EU-EC-10008805464 | | 2021-05-27 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16729** | click or scan EU-EC-10008805414 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acidosis (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute kidney injury (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ascites (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Encephalopathy (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epistaxis (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Feeling abnormal (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemodynamic instability (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatic function abnormal (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatomegaly (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic hepatitis (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Periportal oedema (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary infarction (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Right ventricular dysfunction (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Right ventricular failure (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16730 | click or scan EU-EC-10008805387 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16731 | click or scan EU-EC-10008805372 | | 2021-05-27 | Non Healthcare Professional | Non EEA | Not Specified | Female | Lymphoma (2wk - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16732 | click or scan EU-EC-10008805193 | | 2021-05-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Epistaxis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16733 | click or scan EU-EC-10008804952 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest tube insertion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal replacement therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombectomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 16734 | click or scan EU-EC-10008804518 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16735 | click or scan EU-EC-10008804152 | | 2021-05-27 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 16736 | click or scan EU-EC-10008804092 | | 2021-05-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 16737 | click or scan EU-EC-10008804007 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sputum discoloured (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16738 | click or scan EU-EC-10008803757 | | 2021-05-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16739** | click or scan EU-EC-10008803686 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Brain stem thrombosis (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16740** | click or scan EU-EC-10008803668 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Angiopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| **16741** | click or scan EU-EC-10008803487 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthma (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16742** | click or scan EU-EC-10008803340 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (18d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (18d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (18d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (18d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16743** | click or scan EU-EC-10008803218 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Autoimmune disorder (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood creatinine increased (n/a - Fatal - **Results in Death**), Blood disorder (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood pressure decreased (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood sodium decreased (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Enzyme level increased (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fluid retention (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemoglobin decreased (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (57d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic enzyme increased (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypopnoea (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Increased tendency to bruise (57d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Joint swelling (30d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mobility decreased (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (30d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (56d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (30d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (30d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superficial vein thrombosis (30d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination complication (57d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16744** | click or scan EU-EC-10008802401 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16745 | click or scan EU-EC-10008802362 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16746 | click or scan EU-EC-10008802272 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral thrombosis (5d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (5d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hemiplegia (2d - Fatal - **Results in Death**, Other Medically Important Condition), Palpitations (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16747 | click or scan EU-EC-10008802213 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Food refusal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [INFLUENZA VACCINE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 16748 | click or scan EU-EC-10008802207 | | 2021-05-27 | Healthcare Professional | EEA | 18-64 Years | Female | Craniocerebral injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Head injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subdural haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - 1mL - Intramuscular]) |
| 16749 | click or scan EU-EC-10008802206 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Intestinal obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16750 | click or scan EU-EC-10008802146 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16751 | click or scan EU-EC-10008802090 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16752 | click or scan EU-EC-10008801872 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Erythema (1d - Fatal - **Results in Death**), Oedema peripheral (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1mo - .3mL - Intramuscular]) |
| 16753 | click or scan EU-EC-10008801817 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16754 | click or scan EU-EC-10008801612 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16755 | click or scan EU-EC-10008801525 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aggression (n/a - Unknown - ), Agitation (n/a - Unknown - ), Anger (n/a - Unknown - ), Cognitive disorder (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diet refusal (n/a - Unknown - ), Fall (n/a - Unknown - ), Fluid intake reduced (n/a - Unknown - ), Hallucination (n/a - Unknown - Other Medically Important Condition), Irritability (n/a - Unknown - ), Neurological symptom (n/a - Unknown - ), Paranoia (n/a - Unknown - ), Screaming (n/a - Unknown - ), Wheelchair user (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16756 | click or scan EU-EC-10008801392 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Carotid artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16757 | click or scan EU-EC-10008801384 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16758 | click or scan EU-EC-10008801346 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16759 | click or scan EU-EC-10008800565 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16760 | click or scan EU-EC-10008800519 | | 2021-05-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16761 | click or scan EU-EC-10008800356 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 16762 | click or scan EU-EC-10008800199 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Type 2 diabetes mellitus (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16763 | click or scan EU-EC-10008800120 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis coronary artery (2d - Fatal - **Results in Death**), Cold sweat (n/a - Unknown - ), Coronary artery occlusion (2d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Hypotension (n/a - Unknown - ), Paraesthesia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16764 | click or scan EU-EC-10008799972 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16765** | click or scan EU-EC-10008799956 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Bradycardia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16766** | click or scan EU-EC-10008799775 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (2d - Fatal - **Results in Death**), Peripheral coldness (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16767** | click or scan EU-EC-10008799712 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16768** | click or scan EU-EC-10008799623 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16769** | click or scan EU-EC-10008799579 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Moaning (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16770** | click or scan EU-EC-10008799543 | | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **16771** | click or scan EU-EC-10008799479 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| **16772** | click or scan EU-EC-10008799420 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac valve vegetation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cognitive disorder (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Device related bacteraemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mental status changes (n/a - Fatal - **Results in Death**), Motor dysfunction (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16773** | click or scan EU-EC-10008799356 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16774** | click or scan EU-EC-10008799252 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agonal respiration (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (0d - Fatal - **Results in Death**, Other Medically Important Condition), Feeling hot (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Injection site pain (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16775** | click or scan EU-EC-10008798691 | | 2021-05-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16776** | click or scan EU-EC-10008798637 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Illness (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16777** | click or scan EU-EC-10008798544 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16778** | click or scan EU-EC-10008798493 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Carotid artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16779** | click or scan EU-EC-10008798377 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16780** | click or scan EU-EC-10008798268 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16781** | click or scan EU-EC-10008798222 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16782** | click or scan EU-EC-10008798185 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| **16783** | click or scan EU-EC-10008798048 | | 2021-05-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16784 | click or scan EU-EC-10008798047 | | 2021-05-27 | Healthcare Professional | EEA | More than 85 Years | Female | Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Toxic epidermal necrolysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 16785 | click or scan EU-EC-10008798040 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 16786 | click or scan EU-EC-10008798039 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 16787 | click or scan EU-EC-10008797744 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16788 | click or scan EU-EC-10008797743 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Housebound (1d - Fatal - **Results in Death**), Illness (1d - Fatal - **Results in Death**), Mobility decreased (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16789 | click or scan EU-EC-10008797697 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Apnoea (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16790 | click or scan EU-EC-10008797663 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16791 | click or scan EU-EC-10008797655 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16792 | click or scan EU-EC-10008797644 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16793 | click or scan EU-EC-10008797617 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16794 | click or scan EU-EC-10008797608 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Embolic stroke (2d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Malaise (2d - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16795 | click or scan EU-EC-10008797559 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16796 | click or scan EU-EC-10008797558 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16797 | click or scan EU-EC-10008797556 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16798 | click or scan EU-EC-10008797534 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood glucose increased (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16799 | click or scan EU-EC-10008797525 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16800 | click or scan EU-EC-10008797448 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| 16801 | click or scan EU-EC-10008797425 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16802 | click or scan EU-EC-10008797385 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delusion (n/a - Fatal - **Results in Death**), Hallucination (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16803 | click or scan EU-EC-10008797368 | | 2021-05-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 16804 | click or scan EU-EC-10008797029 | | 2021-05-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16805 | click or scan EU-EC-10008796982 | | 2021-05-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16806 | click or scan EU-EC-10008796531 | | 2021-05-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16807 | click or scan EU-EC-10008796062 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Haematemesis (1d - Fatal - **Results in Death**), Intestinal ischaemia (1d - Fatal - **Results in Death**), Melaena (1d - Fatal - **Results in Death**), Mesenteric vein thrombosis (1d - Fatal - **Results in Death**), Portal vein thrombosis (1d - Fatal - **Results in Death**), Splenic vein thrombosis (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16808 | click or scan EU-EC-10008796008 | | 2021-05-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiopulmonary failure (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 16809 | click or scan EU-EC-10008795995 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (1d - Fatal - **Results in Death**), Intestinal ischaemia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 16810 | click or scan EU-EC-10008795651 | | 2021-05-27 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 16811 | click or scan EU-EC-10008795448 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure acute (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 16812 | click or scan EU-EC-10008795423 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a - More in ICSR]) |
| 16813 | click or scan EU-EC-10008795385 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16814 | click or scan EU-EC-10008795306 | | 2021-05-26 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16815** | click or scan EU-EC-10008795305 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Agonal respiration (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16816** | click or scan EU-EC-10008795280 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (35d - Fatal - **Results in Death**), Confusional state (35d - Fatal - **Results in Death**), Death (35d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (35d - Fatal - **Results in Death**), Delirium (35d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (35d - Fatal - **Results in Death**), Fatigue (35d - Fatal - **Results in Death**), Headache (35d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16817** | click or scan EU-EC-10008795218 | | 2021-05-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metastases to lung (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **16818** | click or scan EU-EC-10008795016 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16819** | click or scan EU-EC-10008794989 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16820** | click or scan EU-EC-10008794878 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Lung disorder (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16821** | click or scan EU-EC-10008794867 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (1d - Fatal - **Results in Death**), Cough (1d - Fatal - **Results in Death**), Dizziness (13d - Fatal - **Results in Death**), Feeling abnormal (1d - Fatal - **Results in Death**), Headache (13d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (15d - Fatal - **Results in Death**), Peripheral swelling (15d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Fatal - **Results in Death**), Restlessness (1d - Fatal - **Results in Death**), Vision blurred (13d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16822** | click or scan EU-EC-10008794834 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16823** | click or scan EU-EC-10008794829 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16824** | click or scan EU-EC-10008794729 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Food refusal (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16825** | click or scan EU-EC-10008794701 |  | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16826** | click or scan EU-EC-10008794695 |  | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary artery embolism (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16827** | click or scan EU-EC-10008794475 |  | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16828** | click or scan EU-EC-10008794421 |  | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Absence of immediate treatment response (1d - Fatal - **Results in Death**), Cardiogenic shock (1d - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Intensive care (1d - Fatal - **Results in Death**), Mechanical ventilation (1d - Fatal - **Results in Death**), Pulseless electrical activity (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sedative therapy (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular - More in ICSR]) |
| **16829** | click or scan EU-EC-10008794352 |  | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (2d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Lung consolidation (2d - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Septic shock (2d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16830** | click or scan EU-EC-10008793719 |  | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16831** | click or scan EU-EC-10008793553 |  | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lymph node pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **16832** | click or scan EU-EC-10008793473 |  | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16833** | click or scan EU-EC-10008793352 |  | 2021-05-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **16834** | click or scan EU-EC-10008793117 |  | 2021-05-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16835** | click or scan EU-EC-10008792989 |  | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain natriuretic peptide increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypomagnesaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16836** | click or scan EU-EC-10008792853 |  | 2021-05-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16837** | click or scan EU-EC-10008792785 |  | 2021-05-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Unknown - ), Aphasia (n/a - Unknown - ), COVID-19 (n/a - Unknown - ), Cough (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Delirium (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Food refusal (n/a - Unknown - ), Incoherent (n/a - Unknown - ), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **16838** | click or scan EU-EC-10008792765 |  | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Brain death (0d - Fatal - **Results in Death**), Cardiac arrest (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16839** | click or scan EU-EC-10008792534 |  | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **16840** | click or scan EU-EC-10008792444 |  | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood urine present (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematuria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16841** | click or scan EU-EC-10008792273 |  | 2021-05-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **16842** | click or scan EU-EC-10008792257 |  | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**), Respiratory rate decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **16843** | click or scan EU-EC-10008791970 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16844** | click or scan EU-EC-10008791104 | | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Adrenal haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Adrenal thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haematoma (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **16845** | click or scan EU-EC-10008790911 | | 2021-05-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16846** | click or scan EU-EC-10008790817 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **16847** | click or scan EU-EC-10008790816 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pemphigoid (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]) |
| **16848** | click or scan EU-EC-10008790758 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **16849** | click or scan EU-EC-10008790702 | | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **16850** | click or scan EU-EC-10008790621 | | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Cardiovascular disorder (0d - Fatal - **Results in Death**), Chest pain (0d - Fatal - **Results in Death**), Circulatory collapse (0d - Fatal - **Results in Death**), Foaming at mouth (0d - Fatal - **Results in Death**), Hyperhidrosis (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Sense of oppression (0d - Fatal - **Results in Death**), Skin discolouration (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16851** | click or scan EU-EC-10008790618 | | 2021-05-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16852** | click or scan EU-EC-10008790617 | | 2021-05-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16853 | click or scan EU-EC-10008790616 | | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16854 | click or scan EU-EC-10008790615 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16855 | click or scan EU-EC-10008790614 | | 2021-05-26 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16856 | click or scan EU-EC-10008790148 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16857 | click or scan EU-EC-10008790072 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Pneumonitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16858 | click or scan EU-EC-10008789995 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16859 | click or scan EU-EC-10008789905 | | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 16860 | click or scan EU-EC-10008789243 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bradycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Left ventricular hypertrophy (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16861 | click or scan EU-EC-10008789129 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), Fatigue (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16862 | click or scan EU-EC-10008788971 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Intestinal infarction (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16863 | click or scan EU-EC-10008788704 |  | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (4d - Fatal - **Results in Death**), Epilepsy (4d - Fatal - **Results in Death**), Gaze palsy (4d - Fatal - **Results in Death**), Hemiparesis (4d - Fatal - **Results in Death**), Tongue biting (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16864 | click or scan EU-EC-10008788694 |  | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16865 | click or scan EU-EC-10008788282 |  | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 16866 | click or scan EU-EC-10008788246 |  | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Male | Aphasia (3d - Fatal - **Results in Death**), Basilar artery occlusion (3d - Fatal - **Results in Death**), Brain death (3d - Fatal - **Results in Death**), Coma (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 16867 | click or scan EU-EC-10008788128 |  | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16868 | click or scan EU-EC-10008788061 |  | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 16869 | click or scan EU-EC-10008787990 |  | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16870 | click or scan EU-EC-10008787839 |  | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Epilepsy (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16871 | click or scan EU-EC-10008787727 |  | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Acute pulmonary oedema (0d - Fatal - **Results in Death**), Respiratory failure (0d - Fatal - **Results in Death**), Tachypnoea (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16872 | click or scan EU-EC-10008787639 |  | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**), Cough (6d - Fatal - **Results in Death**), Drug ineffective (6d - Fatal - **Results in Death**), Hypoxia (6d - Fatal - **Results in Death**), Oxygen therapy (6d - Fatal - **Results in Death**), Pyrexia (6d - Fatal - **Results in Death**), Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16873** | click or scan EU-EC-10008786603 | | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Female | Acquired haemophilia (n/a - Fatal - **Results in Death**), Anti factor VIII antibody positive (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **16874** | click or scan EU-EC-10008786361 | | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **16875** | click or scan EU-EC-10008786189 | | 2021-05-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16876** | click or scan EU-EC-10008785740 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Alcohol use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central venous catheterisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Life support (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Substance use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Supraventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxicologic test abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16877** | click or scan EU-EC-10008785489 | | 2021-05-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **16878** | click or scan EU-EC-10008785245 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Abnormal behaviour (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Amnesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16879** | click or scan EU-EC-10008785221 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16880** | click or scan EU-EC-10008784965 | | 2021-05-26 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **16881** | click or scan EU-EC-10008784945 | | 2021-05-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16882** | click or scan EU-EC-10008784936 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**), Vascular stent thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16883** | click or scan EU-EC-10008784847 | | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia viral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16884** | click or scan EU-EC-10008784652 | | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16885** | click or scan EU-EC-10008784241 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coronary artery occlusion (n/a - Not Recovered/Not Resolved - Life Threatening), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16886** | click or scan EU-EC-10008783861 | | 2021-05-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Recovering/Resolving - ), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **16887** | click or scan EU-EC-10008783660 | | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **16888** | click or scan EU-EC-10008783401 | | 2021-05-26 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **16889** | click or scan EU-EC-10008782812 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disorientation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **16890** | click or scan EU-EC-10008782580 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Essential hypertension (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| **16891** | click or scan EU-EC-10008782431 | | 2021-05-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16892 | click or scan EU-EC-10008781805 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 16893 | click or scan EU-EC-10008781705 | | 2021-05-26 | Non Healthcare Professional | EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16894 | click or scan EU-EC-10008781018 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16895 | click or scan EU-EC-10008780933 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16896 | click or scan EU-EC-10008780373 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16897 | click or scan EU-EC-10008780330 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16898 | click or scan EU-EC-10008779781 | | 2021-05-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Balance disorder (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 16899 | click or scan EU-EC-10008779542 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Haematemesis (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 16900 | click or scan EU-EC-10008779362 | | 2021-05-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Unknown - Caused/Prolonged Hospitalisation), Anosmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Productive cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16901 | click or scan EU-EC-10008779345 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16902 | click or scan EU-EC-10008779326 | | 2021-05-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16903 | click or scan EU-EC-10008777038 | | 2021-05-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral ischaemia (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 16904 | click or scan EU-EC-10008776701 | | 2021-05-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Oropharyngeal discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16905 | click or scan EU-EC-10008778438 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Clinical death (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Investigation (n/a - Unknown - ), Myalgia (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - ), Severe acute respiratory syndrome (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16906 | click or scan EU-EC-10008778401 | | 2021-05-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | Abdominal pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Vaccination complication (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16907 | click or scan EU-EC-10008778369 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16908 | click or scan EU-EC-10008778361 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 16909 | click or scan EU-EC-10008778286 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 16910 | click or scan EU-EC-10008778090 | | 2021-05-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Lethargy (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16911 | click or scan EU-EC-10008778071 | | 2021-05-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16912** | click or scan EU-EC-10008777894 | | 2021-05-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **16913** | click or scan EU-EC-10008777564 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16914** | click or scan EU-EC-10008777557 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| **16915** | click or scan EU-EC-10008777556 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16916** | click or scan EU-EC-10008777503 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Limb discomfort (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Pain in jaw (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16917** | click or scan EU-EC-10008777499 | | 2021-05-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Disturbance in attention (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16918** | click or scan EU-EC-10008777451 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Not Recovered/Not Resolved - ), Vaccination failure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16919** | click or scan EU-EC-10008777445 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16920** | click or scan EU-EC-10008777439 | | 2021-05-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Injection site pain (2d - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 16921 | click or scan EU-EC-10008777433 | | 2021-05-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Angina pectoris (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16922 | click or scan EU-EC-10008777408 | | 2021-05-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16923 | click or scan EU-EC-10008777398 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16924 | click or scan EU-EC-10008777351 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 16925 | click or scan EU-EC-10008777251 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 16926 | click or scan EU-EC-10008776636 | | 2021-05-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16927 | click or scan EU-EC-10008776470 | | 2021-05-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (2546min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16928 | click or scan EU-EC-10008776441 | | 2021-05-25 | Healthcare Professional | Non EEA | Not Specified | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 16929 | click or scan EU-EC-10008776140 | | 2021-05-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 16930 | click or scan EU-EC-10008775845 | | 2021-05-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate irregular (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16931** | click or scan EU-EC-10008775698 | | 2021-05-25 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16932** | click or scan EU-EC-10008775644 | | 2021-05-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Bronchitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16933** | click or scan EU-EC-10008775623 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16934** | click or scan EU-EC-10008775529 | | 2021-05-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Breast pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16935** | click or scan EU-EC-10008775520 | | 2021-05-25 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16936** | click or scan EU-EC-10008775481 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Apathy (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Pallor (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ), Respiratory distress (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16937** | click or scan EU-EC-10008775164 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Female | Aspiration (1d - Fatal - **Results in Death**), Pyrexia (2d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **16938** | click or scan EU-EC-10008774790 | | 2021-05-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Impaired healing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Melaena (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **16939** | click or scan EU-EC-10008774788 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16940** | click or scan EU-EC-10008774519 | | 2021-05-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Genital haemorrhage (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Uterine haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16941** | click or scan EU-EC-10008774472 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16942 | click or scan EU-EC-10008774291 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Recovering/Resolving - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Disabling), Chest pain (2wk - Recovering/Resolving - ), Delirium (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (2wk - Recovering/Resolving - ), Nausea (2wk - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 16943 | click or scan EU-EC-10008774173 | | 2021-05-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (3d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (3d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral embolism (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 16944 | click or scan EU-EC-10008773942 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Concomitant disease aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Concomitant disease aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation), Oedema (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**), Vertigo (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 16945 | click or scan EU-EC-10008773564 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 16946 | click or scan EU-EC-10008773112 | | 2021-05-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16947 | click or scan EU-EC-10008773080 | | 2021-05-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 16948 | click or scan EU-EC-10008772998 | | 2021-05-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urticaria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16949 | click or scan EU-EC-10008772494 | | 2021-05-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Pupil fixed (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**), Right ventricular enlargement (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16950 | click or scan EU-EC-10008772480 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 16951 | click or scan EU-EC-10008772408 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16952** | click or scan EU-EC-10008771836 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16953** | click or scan EU-EC-10008771820 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **16954** | click or scan EU-EC-10008771730 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Hypercalcaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16955** | click or scan EU-EC-10008771723 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16956** | click or scan EU-EC-10008771706 | | 2021-05-25 | Non Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Generalised oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16957** | click or scan EU-EC-10008771696 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Influenza like illness (4d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16958** | click or scan EU-EC-10008771691 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16959** | click or scan EU-EC-10008771663 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16960** | click or scan EU-EC-10008771619 | | 2021-05-25 | Healthcare Professional | EEA | Not Specified | Male | Cardiac failure acute (8d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16961** | click or scan EU-EC-10008771596 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (8d - Fatal - **Results in Death**), Pulmonary embolism (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16962** | click or scan EU-EC-10008771582 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16963** | click or scan EU-EC-10008771546 | | 2021-05-25 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16964** | click or scan EU-EC-10008771541 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16965** | click or scan EU-EC-10008771534 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16966** | click or scan EU-EC-10008771532 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **16967** | click or scan EU-EC-10008771047 | | 2021-05-25 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16968** | click or scan EU-EC-10008770956 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **16969** | click or scan EU-EC-10008770918 | | 2021-05-25 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neonatal pneumothorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neonatal respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Premature baby (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **16970** | click or scan EU-EC-10008770909 | | 2021-05-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arterial stenosis (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16971** | click or scan EU-EC-10008770090 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Male | Anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypernatraemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [CEFTRIAXONE, CEFTRIAXONE SODIUM] (S - Antibiotic therapy - Unknown - [n/a - n/a - n/a]) |
| **16972** | click or scan EU-EC-10008770010 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16973** | click or scan EU-EC-10008769827 | | 2021-05-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16974** | click or scan EU-EC-10008769826 | | 2021-05-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aortic dissection (9d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16975** | click or scan EU-EC-10008769771 | | 2021-05-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16976** | click or scan EU-EC-10008769364 | | 2021-05-25 | Healthcare Professional | EEA | More than 85 Years | Male | Chills (3d - Fatal - **Results in Death**), Haematoma (3d - Fatal - **Results in Death**), Pain in extremity (3d - Fatal - **Results in Death**), Pallor (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16977** | click or scan EU-EC-10008769275 | | 2021-05-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (n/a - Unknown - Life Threatening), Snoring (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **16978** | click or scan EU-EC-10008769250 | | 2021-05-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disease recurrence (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Lip swelling (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pharyngeal swelling (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Swelling face (n/a - Unknown - ), Swollen tongue (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16979** | click or scan EU-EC-10008769075 | | 2021-05-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16980** | click or scan EU-EC-10008768548 | | 2021-05-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Movement disorder (1d - Fatal - **Results in Death**), Muscular weakness (16h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16981** | click or scan EU-EC-10008768434 | | 2021-05-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Urinary incontinence (n/a - Fatal - **Results in Death**), Vaccine breakthrough infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16982** | click or scan EU-EC-10008768400 | | 2021-05-25 | Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Unknown - ), Body temperature increased (n/a - Unknown - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Visual impairment (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **16983** | click or scan EU-EC-10008768199 | | 2021-05-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **16984** | click or scan EU-EC-10008768184 | | 2021-05-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Influenza like illness (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - ), Palpitations (n/a - Unknown - Life Threatening), Pneumonia (n/a - Unknown - Life Threatening), Transient ischaemic attack (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16985** | click or scan EU-EC-10008767893 | | 2021-05-25 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| **16986** | click or scan EU-EC-10008766700 | | 2021-05-24 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **16987** | click or scan EU-EC-10008766632 | | 2021-05-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain death (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16988** | click or scan EU-EC-10008766620 | | 2021-05-24 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16989** | click or scan EU-EC-10008766292 | | 2021-05-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **16990** | click or scan EU-EC-10008766243 | | 2021-05-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cheyne-Stokes respiration (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diet refusal (n/a - Unknown - Life Threatening), General physical health deterioration (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **16991** | click or scan EU-EC-10008766210 | | 2021-05-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **16992** | click or scan EU-EC-10008766179 | | 2021-05-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 16993 | click or scan EU-EC-10008765923 | | 2021-05-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16994 | click or scan EU-EC-10008765621 | | 2021-05-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 16995 | click or scan EU-EC-10008765445 | | 2021-05-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 16996 | click or scan EU-EC-10008764826 | | 2021-05-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| 16997 | click or scan EU-EC-10008764626 | | 2021-05-24 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 16998 | click or scan EU-EC-10008764278 | | 2021-05-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 16999 | click or scan EU-EC-10008764047 | | 2021-05-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17000 | click or scan EU-EC-10008763617 | | 2021-05-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17001 | click or scan EU-EC-10008763440 | | 2021-05-24 | Non Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mobility decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17002 | click or scan EU-EC-10008763416 | | 2021-05-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17003 | click or scan EU-EC-10008763353 |  | 2021-05-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17004 | click or scan EU-EC-10008763188 |  | 2021-05-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17005 | click or scan EU-EC-10008762889 |  | 2021-05-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17006 | click or scan EU-EC-10008762666 |  | 2021-05-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (1d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17007 | click or scan EU-EC-10008762476 |  | 2021-05-24 | Healthcare Professional | EEA | More than 85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17008 | click or scan EU-EC-10008762433 |  | 2021-05-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17009 | click or scan EU-EC-10008762080 |  | 2021-05-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17010 | click or scan EU-EC-10008761797 |  | 2021-05-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypophagia (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17011 | click or scan EU-EC-10008760877 |  | 2021-05-24 | Healthcare Professional | EEA | 65-85 Years | Male | Portal vein thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17012 | click or scan EU-EC-10008760299 |  | 2021-05-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17013 | click or scan EU-EC-10008760177 | | 2021-05-24 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Suprapubic pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 17014 | click or scan EU-EC-10008759785 | | 2021-05-24 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 17015 | click or scan EU-EC-10008758452 | | 2021-05-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**), Vaccination failure (13d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17016 | click or scan EU-EC-10008758311 | | 2021-05-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17017 | click or scan EU-EC-10008756427 | | 2021-05-24 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17018 | click or scan EU-EC-10008756089 | | 2021-05-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17019 | click or scan EU-EC-10008754969 | | 2021-05-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Body temperature decreased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17020 | click or scan EU-EC-10008754965 | | 2021-05-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17021 | click or scan EU-EC-10008754963 | | 2021-05-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Incoherent (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17022 | click or scan EU-EC-10008754959 | | 2021-05-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17023 | click or scan EU-EC-10008752720 | | 2021-05-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17024 | click or scan EU-EC-10008752718 | | 2021-05-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17025 | click or scan EU-EC-10008752715 | | 2021-05-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17026 | click or scan EU-EC-10008752714 | | 2021-05-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17027 | click or scan EU-EC-10008752712 | | 2021-05-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17028 | click or scan EU-EC-10008752711 | | 2021-05-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - ), Mouth haemorrhage (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17029 | click or scan EU-EC-10008752281 | | 2021-05-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17030 | click or scan EU-EC-10008752077 | | 2021-05-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17031 | click or scan EU-EC-10008751675 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17032** | click or scan EU-EC-10008751635 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **17033** | click or scan EU-EC-10008750396 | | 2021-05-22 | Healthcare Professional | Non EEA | Not Specified | Female | Contusion (n/a - Unknown - **Results in Death**), Dizziness (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17034** | click or scan EU-EC-10008750386 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17035** | click or scan EU-EC-10008750370 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiac ventricular thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Pain (n/a - Unknown - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **17036** | click or scan EU-EC-10008750367 | | 2021-05-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Spontaneous haematoma (2d - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (2d - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **17037** | click or scan EU-EC-10008750365 | | 2021-05-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening), Fibrosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Left ventricular hypertrophy (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **17038** | click or scan EU-EC-10008749580 | | 2021-05-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Vasculitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **17039** | click or scan EU-EC-10008749569 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (39d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **17040** | click or scan EU-EC-10008749107 | | 2021-05-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **17041** | click or scan EU-EC-10008749010 | | 2021-05-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrioventricular block complete (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Extrasystoles (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular hypertrophy (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17042** | click or scan EU-EC-10008748884 | | 2021-05-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Sepsis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17043** | click or scan EU-EC-10008748872 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (1d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **17044** | click or scan EU-EC-10008748857 | | 2021-05-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - n/a]) |
| **17045** | click or scan EU-EC-10008748851 | | 2021-05-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Influenza like illness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17046** | click or scan EU-EC-10008748850 | | 2021-05-22 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17047** | click or scan EU-EC-10008748801 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17048** | click or scan EU-EC-10008748784 | | 2021-05-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Lethargy (1d - Recovered/Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17049** | click or scan EU-EC-10008748765 | | 2021-05-22 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Cerebral haemorrhage (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17050** | click or scan EU-EC-10008748719 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Balance disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Labyrinthitis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Migraine (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17051** | click or scan EU-EC-10008745202 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17052 | click or scan EU-EC-10008744019 | | 2021-05-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Haemorrhagic cerebral infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17053 | click or scan EU-EC-10008743999 | | 2021-05-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetes insipidus (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intraventricular haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mydriasis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urine output increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17054 | click or scan EU-EC-10008743735 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (18h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Purpura (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17055 | click or scan EU-EC-10008743721 | | 2021-05-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17056 | click or scan EU-EC-10008743706 | | 2021-05-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Thrombosis (1d - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17057 | click or scan EU-EC-10008743019 | | 2021-05-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17058 | click or scan EU-EC-10008742999 | | 2021-05-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17059 | click or scan EU-EC-10008742836 | | 2021-05-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17060 | click or scan EU-EC-10008742268 | | 2021-05-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17061 | click or scan EU-EC-10008742103 |  | 2021-05-22 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17062 | click or scan EU-EC-10008739400 |  | 2021-05-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17063 | click or scan EU-EC-10008739354 |  | 2021-05-22 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**), Cardio-respiratory arrest (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17064 | click or scan EU-EC-10008741005 |  | 2021-05-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Hypopnoea (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17065 | click or scan EU-EC-10008740824 |  | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17066 | click or scan EU-EC-10008740702 |  | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 17067 | click or scan EU-EC-10008740685 |  | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 17068 | click or scan EU-EC-10008740495 |  | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17069 | click or scan EU-EC-10008740355 |  | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Deep vein thrombosis (4d - Fatal - **Results in Death**), Pulmonary embolism (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 17070 | click or scan EU-EC-10008740312 |  | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary thrombosis (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17071 | click or scan EU-EC-10008739737 |  | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Subdural haematoma (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17072 | click or scan EU-EC-10008738655 |  | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17073 | click or scan EU-EC-10008738629 |  | 2021-05-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Recovered/Resolved - Other Medically Important Condition), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Recovered/Resolved - Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17074 | click or scan EU-EC-10008738238 |  | 2021-05-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Infarction (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17075 | click or scan EU-EC-10008738210 |  | 2021-05-21 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17076 | click or scan EU-EC-10008738046 |  | 2021-05-21 | Non Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17077 | click or scan EU-EC-10008738000 |  | 2021-05-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 17078 | click or scan EU-EC-10008737833 |  | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Leg amputation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Postoperative wound complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 17079 | click or scan EU-EC-10008737336 |  | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17080 | click or scan EU-EC-10008736878 |  | 2021-05-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Recovering/Resolving - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Recovered/Resolved - ), Insomnia (n/a - Recovered/Resolved - ), Malaise (2d - Recovering/Resolving - ), Nausea (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17081** | click or scan EU-EC-10008736778 | | 2021-05-21 | Healthcare Professional | Non EEA | Not Specified | Male | Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **17082** | click or scan EU-EC-10008736375 | | 2021-05-21 | Healthcare Professional | Non EEA | Not Specified | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **17083** | click or scan EU-EC-10008735524 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Intestinal ischaemia (2d - Fatal - **Results in Death**), Renal ischaemia (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Oral]) |
| **17084** | click or scan EU-EC-10008735433 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **17085** | click or scan EU-EC-10008735421 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| **17086** | click or scan EU-EC-10008735408 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **17087** | click or scan EU-EC-10008735393 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Male | Guillain-Barre syndrome (n/a - Recovering/Resolving - Life Threatening), Intestinal infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **17088** | click or scan EU-EC-10008735387 | | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17089** | click or scan EU-EC-10008735386 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17090** | click or scan EU-EC-10008735368 | | 2021-05-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17091** | click or scan EU-EC-10008735366 | | 2021-05-21 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **17092** | click or scan EU-EC-10008735350 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| **17093** | click or scan EU-EC-10008735339 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **17094** | click or scan EU-EC-10008735325 | | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **17095** | click or scan EU-EC-10008735128 | | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Asthma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17096** | click or scan EU-EC-10008735124 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agitation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17097** | click or scan EU-EC-10008735115 | | 2021-05-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Gastric haemorrhage (n/a - Unknown - Other Medically Important Condition), Haematochezia (n/a - Unknown - Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Renal haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Urinary bladder haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17098** | click or scan EU-EC-10008735100 | | 2021-05-21 | Healthcare Professional | Non EEA | Not Specified | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17099** | click or scan EU-EC-10008734678 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17100** | click or scan EU-EC-10008734651 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Hyperglycaemia (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17101 | click or scan EU-EC-10008734582 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 17102 | click or scan EU-EC-10008734516 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - ), Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Anaemia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Azotaemia (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - Other Medically Important Condition), Hyperphosphataemia (n/a - Unknown - ), Hyperuricaemia (n/a - Unknown - ), Hyponatraemia (n/a - Unknown - ), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Malnutrition (n/a - Unknown - ), Metabolic acidosis (n/a - Unknown - ), Metabolic encephalopathy (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Waist circumference increased (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17103 | click or scan EU-EC-10008734226 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiration abnormal (1d - Unknown - Other Medically Important Condition), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17104 | click or scan EU-EC-10008733783 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Pneumonia (2d - Unknown - Other Medically Important Condition), Unresponsive to stimuli (2d - Unknown - Other Medically Important Condition), Vomiting (2d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17105 | click or scan EU-EC-10008733777 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (19d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (19d - Unknown - Other Medically Important Condition), Fatigue (19d - Unknown - Other Medically Important Condition), Haemoptysis (19d - Unknown - Life Threatening), Pallor (19d - Unknown - Other Medically Important Condition), Rectal haemorrhage (19d - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17106 | click or scan EU-EC-10008733500 | | 2021-05-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 17107 | click or scan EU-EC-10008733397 | | 2021-05-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anticoagulant therapy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Autopsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17108 | click or scan EU-EC-10008733315 | | 2021-05-21 | Healthcare Professional | Non EEA | Not Specified | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17109 | click or scan EU-EC-10008733089 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17110 | click or scan EU-EC-10008733039 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Unknown - Other Medically Important Condition), Mental impairment (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17111 | click or scan EU-EC-10008732958 | | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17112 | click or scan EU-EC-10008732620 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Male | Intracranial aneurysm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17113 | click or scan EU-EC-10008732599 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17114 | click or scan EU-EC-10008732374 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17115 | click or scan EU-EC-10008732362 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17116 | click or scan EU-EC-10008732288 | | 2021-05-21 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17117 | click or scan EU-EC-10008731818 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (1d - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (1d - Unknown - ), Pneumonia (1d - Unknown - Other Medically Important Condition), Productive cough (1d - Unknown - ), Pyrexia (1d - Unknown - ), Tremor (1d - Unknown - ), Vomiting (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17118 | click or scan EU-EC-10008731514 | | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17119 | click or scan EU-EC-10008731469 | | 2021-05-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17120 | click or scan EU-EC-10008730752 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebrovascular disorder (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17121** | click or scan EU-EC-10008730637 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17122** | click or scan EU-EC-10008729971 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17123** | click or scan EU-EC-10008729965 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17124** | click or scan EU-EC-10008729963 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superinfection bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17125** | click or scan EU-EC-10008729957 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Constipation (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Sepsis syndrome (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17126** | click or scan EU-EC-10008729953 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Vision blurred (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17127** | click or scan EU-EC-10008729941 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17128** | click or scan EU-EC-10008729613 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **17129** | click or scan EU-EC-10008729212 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **17130** | click or scan EU-EC-10008728762 | | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17131 | click or scan EU-EC-10008728752 |  | 2021-05-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17132 | click or scan EU-EC-10008728740 |  | 2021-05-21 | Non Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17133 | click or scan EU-EC-10008728736 |  | 2021-05-21 | Non Healthcare Professional | EEA | Not Specified | Female | Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Brain oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Vascular occlusion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17134 | click or scan EU-EC-10008728726 |  | 2021-05-21 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17135 | click or scan EU-EC-10008728705 |  | 2021-05-21 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17136 | click or scan EU-EC-10008728699 |  | 2021-05-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Blood glucose decreased (n/a - Fatal - **Results in Death**), Diabetic coma (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17137 | click or scan EU-EC-10008728427 |  | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17138 | click or scan EU-EC-10008728343 |  | 2021-05-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chills (2d - Recovered/Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Seizure (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17139 | click or scan EU-EC-10008728012 |  | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17140 | click or scan EU-EC-10008727606 |  | 2021-05-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17141 | click or scan EU-EC-10008727588 | | 2021-05-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Unknown - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17142 | click or scan EU-EC-10008727586 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure increased (n/a - Unknown - ), Cardiac death (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17143 | click or scan EU-EC-10008727579 | | 2021-05-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17144 | click or scan EU-EC-10008727335 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypervolaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 17145 | click or scan EU-EC-10008727255 | | 2021-05-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 17146 | click or scan EU-EC-10008727206 | | 2021-05-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Unknown - ), Diabetes mellitus (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17147 | click or scan EU-EC-10008727182 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Face injury (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17148 | click or scan EU-EC-10008727178 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (12d - Fatal - **Results in Death**), Myocardial infarction (12d - Fatal - **Results in Death**), Pulmonary oedema (12d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17149 | click or scan EU-EC-10008727062 | | 2021-05-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Femur fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 17150 | click or scan EU-EC-10008726942 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Staphylococcal sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17151 | click or scan EU-EC-10008726913 | | 2021-05-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17152 | click or scan EU-EC-10008726862 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bacteraemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Neutropenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sputum discoloured (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17153 | click or scan EU-EC-10008726854 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial flutter (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrioventricular block (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17154 | click or scan EU-EC-10008726846 | | 2021-05-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Atelectasis (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), General symptom (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary mass (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17155 | click or scan EU-EC-10008726803 | | 2021-05-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatosplenomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17156 | click or scan EU-EC-10008726732 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17157 | click or scan EU-EC-10008726512 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | Injection site ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17158 | click or scan EU-EC-10008726494 | | 2021-05-21 | Healthcare Professional | EEA | More than 85 Years | Female | SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17159 | click or scan EU-EC-10008726299 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17160 | click or scan EU-EC-10008726204 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| 17161 | click or scan EU-EC-10008726026 | | 2021-05-21 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (0d - Fatal - **Results in Death**), Feeling abnormal (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Oxygen saturation decreased (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17162 | click or scan EU-EC-10008725830 | | 2021-05-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Unknown - Other Medically Important Condition), Encephalopathy (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Haematochezia (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Melaena (n/a - Unknown - Other Medically Important Condition), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17163 | click or scan EU-EC-10008725674 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17164 | click or scan EU-EC-10008725672 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17165 | click or scan EU-EC-10008725643 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypercapnia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary congestion (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory acidosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17166 | click or scan EU-EC-10008725636 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17167 | click or scan EU-EC-10008725321 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17168 | click or scan EU-EC-10008725272 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (1d - Recovered/Resolved - ), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 17169 | click or scan EU-EC-10008725245 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (1d - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Oliguria (1d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia pseudomonal (1d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17170 | click or scan EU-EC-10008725220 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17171 | click or scan EU-EC-10008725216 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17172 | click or scan EU-EC-10008725100 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17173 | click or scan EU-EC-10008725094 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hypopnoea (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17174 | click or scan EU-EC-10008725091 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Condition aggravated (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17175 | click or scan EU-EC-10008725015 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - ), Cough (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17176 | click or scan EU-EC-10008724957 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17177 | click or scan EU-EC-10008724930 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Unknown - ), Dysstasia (n/a - Unknown - ), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17178 | click or scan EU-EC-10008724870 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17179 | click or scan EU-EC-10008724829 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17180 | click or scan EU-EC-10008724764 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17181 | click or scan EU-EC-10008724732 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17182 | click or scan EU-EC-10008724677 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17183 | click or scan EU-EC-10008724654 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (3d - Unknown - Caused/Prolonged Hospitalisation), Dyspepsia (1d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (3d - Unknown - Caused/Prolonged Hospitalisation), Headache (3d - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (3d - Unknown - Caused/Prolonged Hospitalisation), Vomiting (1d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17184 | click or scan EU-EC-10008724651 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (3d - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17185 | click or scan EU-EC-10008724417 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17186 | click or scan EU-EC-10008724313 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Female | Cold sweat (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17187 | click or scan EU-EC-10008724045 | | 2021-05-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 17188 | click or scan EU-EC-10008723985 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17189 | click or scan EU-EC-10008723908 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetic ketoacidosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspepsia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17190 | click or scan EU-EC-10008723840 | | 2021-05-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 17191 | click or scan EU-EC-10008723736 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiomegaly (2d - Fatal - **Results in Death**), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (2d - Unknown - ), Pain in extremity (2d - Unknown - ), Renal disorder (2d - Fatal - **Results in Death**), Vomiting (2d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17192 | click or scan EU-EC-10008723720 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Mental status changes (n/a - Unknown - ), Status epilepticus (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17193 | click or scan EU-EC-10008723640 | | 2021-05-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17194 | click or scan EU-EC-10008723628 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17195 | click or scan EU-EC-10008723620 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17196 | click or scan EU-EC-10008723346 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17197 | click or scan EU-EC-10008723190 | | 2021-05-20 | Non Healthcare Professional | EEA | Not Specified | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Sensory loss (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17198 | click or scan EU-EC-10008722970 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17199 | click or scan EU-EC-10008722892 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Epistaxis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17200** | click or scan EU-EC-10008722882 | | 2021-05-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Apraxia (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypokinesia (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17201** | click or scan EU-EC-10008722840 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (2d - Unknown - Other Medically Important Condition), Atrial fibrillation (2d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Unknown - Other Medically Important Condition), Hypotension (2d - Unknown - Other Medically Important Condition), Oedema (2d - Unknown - Other Medically Important Condition), Tachycardia (2d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17202** | click or scan EU-EC-10008722551 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17203** | click or scan EU-EC-10008722297 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **17204** | click or scan EU-EC-10008722235 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown - ), Haemorrhage intracranial (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17205** | click or scan EU-EC-10008722099 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17206** | click or scan EU-EC-10008721984 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (1d - Unknown - Other Medically Important Condition), Cough (1d - Unknown - Other Medically Important Condition), Dyspnoea (1d - Unknown - Other Medically Important Condition), Muscle spasms (1d - Unknown - Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17207** | click or scan EU-EC-10008721932 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (1d - Unknown - ), Pain (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17208** | click or scan EU-EC-10008721849 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Pallor (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **17209** | click or scan EU-EC-10008721704 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17210 | click or scan EU-EC-10008721657 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fall (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17211 | click or scan EU-EC-10008721423 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17212 | click or scan EU-EC-10008721244 | | 2021-05-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspepsia (n/a - Unknown - ), Ischaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Myocardial rupture (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ), Paraesthesia (n/a - Unknown - ), Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17213 | click or scan EU-EC-10008720955 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17214 | click or scan EU-EC-10008720951 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (2d - Fatal - **Results in Death**), Septic shock (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17215 | click or scan EU-EC-10008720773 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Arterial rupture (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17216 | click or scan EU-EC-10008720716 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17217 | click or scan EU-EC-10008720652 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aneurysm ruptured (15d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (18d - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pyrexia (18d - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (15d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17218 | click or scan EU-EC-10008720210 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17219 | click or scan EU-EC-10008720199 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17220 | click or scan EU-EC-10008719565 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Female | Malaise (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17221 | click or scan EU-EC-10008719167 | | 2021-05-20 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17222 | click or scan EU-EC-10008719163 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17223 | click or scan EU-EC-10008719147 | | 2021-05-20 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 17224 | click or scan EU-EC-10008719079 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Hypoglycaemia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17225 | click or scan EU-EC-10008718914 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood magnesium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardioversion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Catheterisation cardiac (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Electrocardiogram ST segment depression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Full blood count (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell volume decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic function test normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in jaw (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Positive airway pressure therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), QRS axis abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rales (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vascular graft occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vascular graft thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17226** | click or scan EU-EC-10008718880 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **17227** | click or scan EU-EC-10008718797 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17228** | click or scan EU-EC-10008718728 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17229** | click or scan EU-EC-10008718665 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **17230** | click or scan EU-EC-10008718567 | | 2021-05-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17231** | click or scan EU-EC-10008718119 | | 2021-05-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **17232** | click or scan EU-EC-10008717827 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17233** | click or scan EU-EC-10008717674 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **17234** | click or scan EU-EC-10008717498 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **17235** | click or scan EU-EC-10008717366 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17236 | click or scan EU-EC-10008717251 | | 2021-05-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac disorder (2d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (2d - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skull fracture (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17237 | click or scan EU-EC-10008717247 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain lower (n/a - Unknown - ), Cardiac death (0d - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17238 | click or scan EU-EC-10008717188 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 17239 | click or scan EU-EC-10008717129 | | 2021-05-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17240 | click or scan EU-EC-10008717044 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17241 | click or scan EU-EC-10008717015 | | 2021-05-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17242 | click or scan EU-EC-10008716645 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17243 | click or scan EU-EC-10008716559 | | 2021-05-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17244 | click or scan EU-EC-10008716169 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (1d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (1d - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17245 | click or scan EU-EC-10008715722 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Injection site pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17246 | click or scan EU-EC-10008715702 | | 2021-05-20 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17247 | click or scan EU-EC-10008714457 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17248 | click or scan EU-EC-10008714262 | | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 17249 | click or scan EU-EC-10008714260 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17250 | click or scan EU-EC-10008714011 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disease progression (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17251 | click or scan EU-EC-10008713839 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17252 | click or scan EU-EC-10008713796 | | 2021-05-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17253 | click or scan EU-EC-10008713757 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17254 | click or scan EU-EC-10008713754 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma scale (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Ejection fraction decreased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Right ventricular hypertrophy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17255 | click or scan EU-EC-10008713745 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17256 | click or scan EU-EC-10008713486 | | 2021-05-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17257 | click or scan EU-EC-10008713136 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 17258 | click or scan EU-EC-10008713067 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17259 | click or scan EU-EC-10008712782 | | 2021-05-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Chills (n/a - Unknown - ), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Hypoaesthesia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17260 | click or scan EU-EC-10008712757 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17261 | click or scan EU-EC-10008712749 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17262 | click or scan EU-EC-10008712732 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17263 | click or scan EU-EC-10008712712 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17264 | click or scan EU-EC-10008712232 | | 2021-05-20 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 17265 | click or scan EU-EC-10008712207 | | 2021-05-20 | Non Healthcare Professional | EEA | Not Specified | Male | Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17266 | click or scan EU-EC-10008712141 |  | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1440min - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17267 | click or scan EU-EC-10008712139 |  | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17268 | click or scan EU-EC-10008712138 |  | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17269 | click or scan EU-EC-10008712116 |  | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypersomnia (n/a - Unknown - Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17270 | click or scan EU-EC-10008712112 |  | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17271 | click or scan EU-EC-10008712110 |  | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting projectile (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17272 | click or scan EU-EC-10008712109 |  | 2021-05-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Incomplete course of vaccination (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17273 | click or scan EU-EC-10008712104 |  | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17274 | click or scan EU-EC-10008712102 |  | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17275 | click or scan EU-EC-10008712101 |  | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Sleep disorder (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17276 | click or scan EU-EC-10008712096 | | 2021-05-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 17277 | click or scan EU-EC-10008712091 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (24d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (24d - Unknown - Caused/Prolonged Hospitalisation), Headache (24d - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (24d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17278 | click or scan EU-EC-10008712089 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17279 | click or scan EU-EC-10008712075 | | 2021-05-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17280 | click or scan EU-EC-10008712070 | | 2021-05-20 | Healthcare Professional | Non EEA | Not Specified | Female | Adverse event (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17281 | click or scan EU-EC-10008711543 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (5d - Fatal - **Results in Death**), Aphasia (5d - Fatal - **Results in Death**), Asthenia (5d - Fatal - **Results in Death**), Cerebrovascular accident (5d - Fatal - **Results in Death**), Headache (5d - Fatal - **Results in Death**), Hemiplegia (5d - Fatal - **Results in Death**), Myalgia (5d - Fatal - **Results in Death**), Sopor (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17282 | click or scan EU-EC-10008711229 | | 2021-05-20 | Healthcare Professional | EEA | More than 85 Years | Female | Infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17283 | click or scan EU-EC-10008711212 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17284 | click or scan EU-EC-10008711111 | | 2021-05-20 | Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 17285 | click or scan EU-EC-10008711025 | | 2021-05-20 | Healthcare Professional | EEA | More than 85 Years | Female | Asymptomatic COVID-19 (19d - Fatal - **Results in Death**), Cough (19d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17286** | click or scan EU-EC-10008708893 | | 2021-05-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (5d - Fatal - **Results in Death**), COVID-19 pneumonia (5d - Fatal - **Results in Death**), Cerebrovascular accident (5d - Fatal - **Results in Death**), Gait disturbance (5d - Fatal - **Results in Death**), Motor dysfunction (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3ug - Intramuscular]) |
| **17287** | click or scan EU-EC-10008708740 | | 2021-05-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebrovascular accident (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **17288** | click or scan EU-EC-10008710571 | | 2021-05-19 | Non Healthcare Professional | EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - n/a - [n/a - n/a - n/a]) |
| **17289** | click or scan EU-EC-10008710390 | | 2021-05-19 | Healthcare Professional | EEA | More than 85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Gastritis (n/a - Fatal - **Results in Death**), Parkinsonism (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **17290** | click or scan EU-EC-10008710381 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood fibrinogen decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Venous thrombosis limb (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **17291** | click or scan EU-EC-10008710364 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17292** | click or scan EU-EC-10008710268 | | 2021-05-19 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Slow response to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **17293** | click or scan EU-EC-10008709438 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **17294** | click or scan EU-EC-10008709185 | | 2021-05-19 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Fasciotomy (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **17295** | click or scan EU-EC-10008708185 | | 2021-05-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17296** | click or scan EU-EC-10008707769 |  | 2021-05-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17297** | click or scan EU-EC-10008707047 |  | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **17298** | click or scan EU-EC-10008707042 |  | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **17299** | click or scan EU-EC-10008707035 |  | 2021-05-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17300** | click or scan EU-EC-10008706904 |  | 2021-05-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17301** | click or scan EU-EC-10008706652 |  | 2021-05-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17302** | click or scan EU-EC-10008706474 |  | 2021-05-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **17303** | click or scan EU-EC-10008706101 |  | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiopulmonary failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17304** | click or scan EU-EC-10008705799 |  | 2021-05-19 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17305** | click or scan EU-EC-10008705790 |  | 2021-05-19 | Healthcare Professional | EEA | 18-64 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17306 | click or scan EU-EC-10008705731 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17307 | click or scan EU-EC-10008705723 | | 2021-05-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (4d - Not Recovered/Not Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Pain (1d - Recovered/Resolved - ), Somnolence (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 17308 | click or scan EU-EC-10008705721 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 17309 | click or scan EU-EC-10008705630 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17310 | click or scan EU-EC-10008705615 | | 2021-05-19 | Healthcare Professional | EEA | 18-64 Years | Male | Hemiparaesthesia (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17311 | click or scan EU-EC-10008705571 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 17312 | click or scan EU-EC-10008705552 | | 2021-05-19 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 17313 | click or scan EU-EC-10008705538 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17314 | click or scan EU-EC-10008705353 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Catheter site erythema (n/a - Fatal - **Results in Death**), Catheter site swelling (n/a - Fatal - **Results in Death**), Catheter site warmth (n/a - Fatal - **Results in Death**), Central venous catheter removal (n/a - Fatal - **Results in Death**), Central venous catheterisation (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17315 | click or scan EU-EC-10008705328 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17316 | click or scan EU-EC-10008704841 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 17317 | click or scan EU-EC-10008704802 | | 2021-05-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17318 | click or scan EU-EC-10008704518 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Encephalopathy (1d - Fatal - **Results in Death**, Other Medically Important Condition), Schizophrenia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17319 | click or scan EU-EC-10008704457 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17320 | click or scan EU-EC-10008704323 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17321 | click or scan EU-EC-10008704270 | | 2021-05-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Body temperature decreased (n/a - Unknown - ), Chills (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - ), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Neuralgia (n/a - Fatal - **Results in Death**), Pruritus (n/a - Unknown - ), Visual impairment (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17322 | click or scan EU-EC-10008704014 | | 2021-05-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17323 | click or scan EU-EC-10008703958 | | 2021-05-19 | Healthcare Professional | EEA | More than 85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17324 | click or scan EU-EC-10008703778 | | 2021-05-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Influenza (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 17325 | click or scan EU-EC-10008703776 | | 2021-05-19 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Confusional state (n/a - Unknown - ), Contusion (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17326 | click or scan EU-EC-10008703410 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17327 | click or scan EU-EC-10008703372 | | 2021-05-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17328 | click or scan EU-EC-10008703273 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anticoagulant therapy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hypercoagulation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Transcutaneous pacing (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17329 | click or scan EU-EC-10008703126 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17330 | click or scan EU-EC-10008703093 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Pancreatitis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 17331 | click or scan EU-EC-10008702658 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Hypertension (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17332 | click or scan EU-EC-10008702649 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17333 | click or scan EU-EC-10008702399 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17334 | click or scan EU-EC-10008702388 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17335 | click or scan EU-EC-10008702218 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17336 | click or scan EU-EC-10008702049 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17337 | click or scan EU-EC-10008702000 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17338 | click or scan EU-EC-10008701933 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17339 | click or scan EU-EC-10008701703 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17340 | click or scan EU-EC-10008701609 | | 2021-05-19 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Vaccination site reaction (n/a - Recovering/Resolving - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 17341 | click or scan EU-EC-10008701292 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17342 | click or scan EU-EC-10008700893 | | 2021-05-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Febrile convulsion (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Irritability (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17343 | click or scan EU-EC-10008700697 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 17344 | click or scan EU-EC-10008700687 | | 2021-05-19 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17345 | click or scan EU-EC-10008700509 | | 2021-05-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17346 | click or scan EU-EC-10008700198 | | 2021-05-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17347 | click or scan EU-EC-10008699873 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiovascular disorder (1d - Fatal - **Results in Death**), Hypertension (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17348 | click or scan EU-EC-10008699817 | | 2021-05-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17349 | click or scan EU-EC-10008699803 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Computerised tomogram thorax abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17350 | click or scan EU-EC-10008699711 | | 2021-05-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17351 | click or scan EU-EC-10008699706 | | 2021-05-19 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17352 | click or scan EU-EC-10008699683 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17353 | click or scan EU-EC-10008699561 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17354 | click or scan EU-EC-10008699283 | | 2021-05-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17355 | click or scan EU-EC-10008698803 | | 2021-05-19 | Healthcare Professional | Non EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17356 | click or scan EU-EC-10008698770 | | 2021-05-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17357 | click or scan EU-EC-10008698298 | | 2021-05-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Activated partial thromboplastin time prolonged (n/a - Not Recovered/Not Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiomyopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Congestive cardiomyopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heart rate increased (n/a - Not Recovered/Not Resolved - ), Left ventricular dysfunction (n/a - Not Recovered/Not Resolved - ), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Pleural effusion (n/a - Not Recovered/Not Resolved - ), Toxicity to various agents (n/a - Not Recovered/Not Resolved - ), Ventricular tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]), ENTRESTO [VALSARTAN, SACUBITRIL] (S - n/a - Not applicable - [n/a - n/a - Unknown]), RIVAROXABAN [RIVAROXABAN] (S - Left ventricular dysfunction - Not applicable - [n/a - n/a - Unknown]) |
| 17358 | click or scan EU-EC-10008697878 | | 2021-05-19 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17359 | click or scan EU-EC-10008697858 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Concomitant disease aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Conjunctivitis (n/a - Unknown - ), Haemodynamic instability (n/a - Not Recovered/Not Resolved - ), Hypercapnia (n/a - Not Recovered/Not Resolved - ), Hypoxia (n/a - Not Recovered/Not Resolved - ), Inflammatory marker increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Not Recovered/Not Resolved - ), Skin lesion (n/a - Unknown - ), Tachycardia (n/a - Not Recovered/Not Resolved - ), Tongue coated (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17360 | click or scan EU-EC-10008696494 | | 2021-05-19 | Healthcare Professional | EEA | 65-85 Years | Female | Gaze palsy (2d - Fatal - **Results in Death**), Seizure (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17361 | click or scan EU-EC-10008695607 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17362 | click or scan EU-EC-10008695547 | | 2021-05-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Critical illness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Food intolerance (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Terminal state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17363 | click or scan EU-EC-10008695450 |  | 2021-05-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (n/a - Unknown - ), Subdural haematoma (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17364 | click or scan EU-EC-10008695306 |  | 2021-05-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17365 | click or scan EU-EC-10008695221 |  | 2021-05-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Hepatic haemorrhage (10d - Fatal - **Results in Death**), Post vaccination syndrome (3d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]), SUTENT [SUNITINIB, SUNITINIB MALATE] (S - Gastrointestinal stromal tumour - Not applicable - [n/a - 60mg - Oral]), [BEMIPARIN SODIUM] (S - Mesenteric artery thrombosis - Dose not changed - [n/a - 1 {DF} - Subcutaneous]) |
| 17366 | click or scan EU-EC-10008695196 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 17367 | click or scan EU-EC-10008695103 |  | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 17368 | click or scan EU-EC-10008694838 |  | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 17369 | click or scan EU-EC-10008694670 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), General physical health deterioration (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pneumonia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17370 | click or scan EU-EC-10008694510 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (7min - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Livedo reticularis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17371 | click or scan EU-EC-10008693720 | | 2021-05-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17372 | click or scan EU-EC-10008693307 | | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebellar stroke (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Deep vein thrombosis (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 17373 | click or scan EU-EC-10008692776 | | 2021-05-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17374 | click or scan EU-EC-10008692632 | | 2021-05-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17375 | click or scan EU-EC-10008692486 | | 2021-05-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17376 | click or scan EU-EC-10008692481 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Recovering/Resolving - ), Haematochezia (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Somnolence (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17377 | click or scan EU-EC-10008692479 | | 2021-05-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17378 | click or scan EU-EC-10008692478 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17379 | click or scan EU-EC-10008692476 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic diathesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**), Vaccination site abscess (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17380 | click or scan EU-EC-10008692474 | | 2021-05-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Neck pain (n/a - Not Recovered/Not Resolved - ), Seizure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17381 | click or scan EU-EC-10008692473 | | 2021-05-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17382 | click or scan EU-EC-10008692471 | | 2021-05-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17383 | click or scan EU-EC-10008692117 | | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial flutter (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Right ventricular failure (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17384 | click or scan EU-EC-10008692055 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17385 | click or scan EU-EC-10008691417 | | 2021-05-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17386 | click or scan EU-EC-10008690800 | | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 17387 | click or scan EU-EC-10008690792 | | 2021-05-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17388 | click or scan EU-EC-10008690739 | | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Respiratory acidosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17389 | click or scan EU-EC-10008690723 | | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (30d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - n/a - Intramuscular]) |
| 17390 | click or scan EU-EC-10008690657 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Vascular graft thrombosis (3d - Recovered/Resolved With Sequelae - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17391 | click or scan EU-EC-10008690237 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17392** | click or scan EU-EC-10008690110 |  | 2021-05-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoedema (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - ), Swelling (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17393** | click or scan EU-EC-10008690056 |  | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **17394** | click or scan EU-EC-10008689675 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **17395** | click or scan EU-EC-10008689580 |  | 2021-05-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hiccups (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **17396** | click or scan EU-EC-10008689564 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | Thrombosis (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **17397** | click or scan EU-EC-10008689559 |  | 2021-05-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Stent placement (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17398** | click or scan EU-EC-10008689514 |  | 2021-05-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Coronary angioplasty (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspepsia (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **17399** | click or scan EU-EC-10008688827 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17400** | click or scan EU-EC-10008688093 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (1d - Fatal - **Results in Death**), Dyspnoea (1h - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (12h - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |
| **17401** | click or scan EU-EC-10008687780 |  | 2021-05-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **17402** | click or scan EU-EC-10008687735 |  | 2021-05-18 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17403** | click or scan EU-EC-10008687647 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **17404** | click or scan EU-EC-10008686216 |  | 2021-05-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17405** | click or scan EU-EC-10008685235 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (24d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17406** | click or scan EU-EC-10008685110 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **17407** | click or scan EU-EC-10008684973 |  | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aneurysm ruptured (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **17408** | click or scan EU-EC-10008684932 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (0d - Fatal - **Results in Death**), Confusional state (0d - Fatal - **Results in Death**), Fatigue (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17409** | click or scan EU-EC-10008684796 |  | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (11d - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (11d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17410** | click or scan EU-EC-10008684391 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17411** | click or scan EU-EC-10008684355 |  | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Arrhythmia (n/a - Fatal - **Results in Death**), Brain injury (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - ), Myoclonus (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Postresuscitation encephalopathy (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **17412** | click or scan EU-EC-10008684276 |  | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17413 | click or scan EU-EC-10008684240 | | 2021-05-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Tachycardia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17414 | click or scan EU-EC-10008684184 | | 2021-05-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17415 | click or scan EU-EC-10008684160 | | 2021-05-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Arterial thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17416 | click or scan EU-EC-10008683952 | | 2021-05-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17417 | click or scan EU-EC-10008683642 | | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure chronic (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17418 | click or scan EU-EC-10008683526 | | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Not Recovered/Not Resolved - ), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Vaccination site pain (3d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - .6mL - Intramuscular]) |
| 17419 | click or scan EU-EC-10008683455 | | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Female | Embolism (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| 17420 | click or scan EU-EC-10008683272 | | 2021-05-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17421 | click or scan EU-EC-10008683235 | | 2021-05-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nervous system disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superior sagittal sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17422 | click or scan EU-EC-10008683023 | | 2021-05-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17423 | click or scan EU-EC-10008682727 | | 2021-05-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Aphasia (20d - Fatal - **Results in Death**), Behaviour disorder (20d - Fatal - **Results in Death**), Muscle rigidity (20d - Fatal - **Results in Death**), Neurological symptom (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| 17424 | click or scan EU-EC-10008682575 | | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (11d - Fatal - **Results in Death**), Pleural effusion (11d - Fatal - **Results in Death**), Respiratory failure (11d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17425 | click or scan EU-EC-10008682559 | | 2021-05-18 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 17426 | click or scan EU-EC-10008682395 | | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (3d - Fatal - **Results in Death**), Condition aggravated (3d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Polyuria (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17427 | click or scan EU-EC-10008682210 | | 2021-05-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17428 | click or scan EU-EC-10008682161 | | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 17429 | click or scan EU-EC-10008682149 | | 2021-05-18 | Healthcare Professional | EEA | 18-64 Years | Female | Purpura (2d - Fatal - **Results in Death**), Sepsis (2d - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17430 | click or scan EU-EC-10008680180 | | 2021-05-18 | Healthcare Professional | EEA | More than 85 Years | Male | Confusional state (30d - Fatal - **Results in Death**), Drop attacks (30d - Fatal - **Results in Death**), Hypoaesthesia oral (30d - Fatal - **Results in Death**), Tongue paralysis (30d - Fatal - **Results in Death**), Transient ischaemic attack (30d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17431 | click or scan EU-EC-10008681339 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Female | Confusional state (15d - Fatal - **Results in Death**), Partial seizures (15d - Fatal - **Results in Death**), Psychomotor hyperactivity (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17432 | click or scan EU-EC-10008681274 | | 2021-05-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17433 | click or scan EU-EC-10008681061 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Axillary vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subclavian vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17434 | click or scan EU-EC-10008681046 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown]) |
| 17435 | click or scan EU-EC-10008681035 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Female | Mesenteric vein thrombosis (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 17436 | click or scan EU-EC-10008681030 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 17437 | click or scan EU-EC-10008680337 | | 2021-05-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17438 | click or scan EU-EC-10008680203 | | 2021-05-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Parenteral]) |
| 17439 | click or scan EU-EC-10008679781 | | 2021-05-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bell's palsy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Facial paresis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Taste disorder (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17440 | click or scan EU-EC-10008679777 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 17441 | click or scan EU-EC-10008679709 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), XARELTO [RIVAROXABAN] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17442 | click or scan EU-EC-10008679674 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | Intracardiac thrombus (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 17443 | click or scan EU-EC-10008679635 | | 2021-05-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Exposure during pregnancy (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 17444 | click or scan EU-EC-10008679574 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Fall (n/a - Unknown - ), Malaise (n/a - Unknown - ), Mydriasis (n/a - Unknown - ), Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition), Pulse absent (n/a - Unknown - ), Pupil fixed (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17445 | click or scan EU-EC-10008679461 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (2mo - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17446 | click or scan EU-EC-10008679458 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17447 | click or scan EU-EC-10008679229 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bradycardia (n/a - Unknown - ), Corneal lesion (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Unknown - ), Hypotension (n/a - Unknown - ), Platelet disorder (n/a - Unknown - ), Sinus arrest (n/a - Unknown - ), Vision blurred (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17448 | click or scan EU-EC-10008679064 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17449 | click or scan EU-EC-10008678787 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17450 | click or scan EU-EC-10008678371 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17451 | click or scan EU-EC-10008678368 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17452 | click or scan EU-EC-10008678341 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17453 | click or scan EU-EC-10008678226 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17454 | click or scan EU-EC-10008678217 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17455 | click or scan EU-EC-10008678211 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17456 | click or scan EU-EC-10008677332 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 17457 | click or scan EU-EC-10008677313 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17458 | click or scan EU-EC-10008677259 | | 2021-05-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Renal impairment (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17459 | click or scan EU-EC-10008677206 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pneumonitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17460 | click or scan EU-EC-10008676934 | | 2021-05-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17461 | click or scan EU-EC-10008676779 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Influenza like illness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17462 | click or scan EU-EC-10008676684 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17463 | click or scan EU-EC-10008676625 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain death (n/a - Unknown - Other Medically Important Condition), Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17464 | click or scan EU-EC-10008676623 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17465 | click or scan EU-EC-10008675929 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17466 | click or scan EU-EC-10008675928 | | 2021-05-17 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombophlebitis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17467 | click or scan EU-EC-10008675921 | | 2021-05-17 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17468 | click or scan EU-EC-10008675870 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 17469 | click or scan EU-EC-10008675869 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17470 | click or scan EU-EC-10008675841 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory distress syndrome (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyelonephritis acute (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17471 | click or scan EU-EC-10008675542 | | 2021-05-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17472 | click or scan EU-EC-10008675208 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 17473 | click or scan EU-EC-10008675201 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| 17474 | click or scan EU-EC-10008675119 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 17475 | click or scan EU-EC-10008675073 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - .3mL - Intramuscular]) |
| 17476 | click or scan EU-EC-10008675040 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (5d - Fatal - **Results in Death**), Cardio-respiratory arrest (5d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 17477 | click or scan EU-EC-10008674993 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - .6mL - Intramuscular]) |
| 17478 | click or scan EU-EC-10008674960 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |
| 17479 | click or scan EU-EC-10008674404 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arthralgia (n/a - Not Recovered/Not Resolved - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Unknown - ), Headache (n/a - Recovered/Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Recovering/Resolving - ), Sneezing (n/a - Unknown - ), Vaccination site pain (n/a - Recovering/Resolving - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17480 | click or scan EU-EC-10008674258 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Escherichia sepsis (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Gallbladder enlargement (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hyperuricaemia (n/a - Fatal - **Results in Death**), Left ventricular hypertrophy (n/a - Fatal - **Results in Death**), Leukopenia (n/a - Fatal - **Results in Death**), Liver function test increased (n/a - Fatal - **Results in Death**), Liver injury (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal cyst (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17481 | click or scan EU-EC-10008674159 | | 2021-05-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (67d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17482 | click or scan EU-EC-10008674115 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17483 | click or scan EU-EC-10008673459 | | 2021-05-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17484 | click or scan EU-EC-10008672785 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |
| 17485 | click or scan EU-EC-10008672407 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17486 | click or scan EU-EC-10008672373 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Mesenteric vascular occlusion (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17487 | click or scan EU-EC-10008672218 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17488 | click or scan EU-EC-10008671931 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17489 | click or scan EU-EC-10008671924 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17490 | click or scan EU-EC-10008671040 | | 2021-05-17 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17491 | click or scan EU-EC-10008670794 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17492 | click or scan EU-EC-10008670679 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling hot (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypervolaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung consolidation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urine output decreased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 17493 | click or scan EU-EC-10008669283 | | 2021-05-17 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular]) |
| 17494 | click or scan EU-EC-10008669019 | | 2021-05-17 | Healthcare Professional | EEA | More than 85 Years | Male | Breath sounds abnormal (n/a - Fatal - **Results in Death**), Cardiac death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 17495 | click or scan EU-EC-10008668798 | | 2021-05-17 | Healthcare Professional | Non EEA | Not Specified | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17496 | click or scan EU-EC-10008668797 | | 2021-05-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Angiopathy (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17497 | click or scan EU-EC-10008668787 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypophagia (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17498 | click or scan EU-EC-10008668404 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17499** | click or scan EU-EC-10008668399 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anticoagulation drug level below therapeutic (9d - Fatal - **Results in Death**, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Autoscopy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (4d - Fatal - **Results in Death**, Other Medically Important Condition), Cognitive disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (4d - Fatal - **Results in Death**, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Off label use (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Not Recovered/Not Resolved - ), Pulmonary haemorrhage (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Transient ischaemic attack (n/a - Unknown - Other Medically Important Condition), Vertebral artery stenosis (n/a - Unknown - Other Medically Important Condition) | APIXABAN [APIXABAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17500** | click or scan EU-EC-10008668357 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Unknown - ), Pneumonitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17501** | click or scan EU-EC-10008668342 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17502** | click or scan EU-EC-10008667965 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial flutter (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [INFLUENZA VACCINE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **17503** | click or scan EU-EC-10008667713 | | 2021-05-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Retching (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **17504** | click or scan EU-EC-10008667696 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **17505** | click or scan EU-EC-10008667694 | | 2021-05-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **17506** | click or scan EU-EC-10008667553 | | 2021-05-17 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory failure (47d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17507 | click or scan EU-EC-10008667521 |  | 2021-05-17 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17508 | click or scan EU-EC-10008666784 |  | 2021-05-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17509 | click or scan EU-EC-10008665980 |  | 2021-05-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17510 | click or scan EU-EC-10008665089 |  | 2021-05-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Flushing (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Muscle spasms (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17511 | click or scan EU-EC-10008663530 |  | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - **Results in Death**), Anuria (n/a - Unknown - **Results in Death**), Aortic thrombosis (6d - Fatal - **Results in Death**), Blister (n/a - Unknown - **Results in Death**), Bradycardia (n/a - Not Recovered/Not Resolved - **Results in Death**), COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiogenic shock (n/a - Not Recovered/Not Resolved - **Results in Death**), Distributive shock (n/a - Not Recovered/Not Resolved - **Results in Death**), Hyperkalaemia (n/a - Unknown - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**), Iliac artery occlusion (n/a - Unknown - **Results in Death**), Livedo reticularis (n/a - Unknown - **Results in Death**), Peripheral ischaemia (n/a - Not Recovered/Not Resolved - **Results in Death**), Renal artery occlusion (n/a - Unknown - **Results in Death**), Renal atrophy (n/a - Unknown - **Results in Death**), Renal infarct (n/a - Not Recovered/Not Resolved - **Results in Death**), Tension (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), Thrombosis in device (n/a - Unknown - **Results in Death**), Vasoplegia syndrome (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17512 | click or scan EU-EC-10008663461 |  | 2021-05-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 17513 | click or scan EU-EC-10008663256 |  | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - 1 {DF} - n/a]) |
| 17514 | click or scan EU-EC-10008662875 |  | 2021-05-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (4d - Fatal - **Results in Death**), Gout (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17515 | click or scan EU-EC-10008661869 |  | 2021-05-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic embolus (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17516 | click or scan EU-EC-10008661866 |  | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Peripheral swelling (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 17517 | click or scan EU-EC-10008661864 |  | 2021-05-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17518 | click or scan EU-EC-10008661833 |  | 2021-05-15 | Healthcare Professional | Non EEA | Not Specified | Female | Extremity necrosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral ischaemia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Retinal vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Venous haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17519 | click or scan EU-EC-10008661751 |  | 2021-05-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 17520 | click or scan EU-EC-10008661378 |  | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (1d - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 17521 | click or scan EU-EC-10008661241 |  | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 17522 | click or scan EU-EC-10008660911 |  | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Congestive cardiomyopathy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Flushing (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Retching (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular hypertrophy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 17523 | click or scan EU-EC-10008660863 |  | 2021-05-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arterial thrombosis (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17524 | click or scan EU-EC-10008660837 |  | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17525** | click or scan EU-EC-10008660831 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17526** | click or scan EU-EC-10008660808 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **17527** | click or scan EU-EC-10008660670 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **17528** | click or scan EU-EC-10008660640 | | 2021-05-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Unknown - **Results in Death**), Chronic respiratory disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **17529** | click or scan EU-EC-10008659771 | | 2021-05-15 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **17530** | click or scan EU-EC-10008659759 | | 2021-05-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **17531** | click or scan EU-EC-10008659755 | | 2021-05-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Abdominal discomfort (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abdominal pain upper (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constipation (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Volvulus (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17532** | click or scan EU-EC-10008659753 | | 2021-05-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Platelet count decreased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **17533** | click or scan EU-EC-10008659752 | | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute hepatic failure (n/a - Fatal - **Results in Death**), Hepatitis acute (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17534 | click or scan EU-EC-10008659720 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 17535 | click or scan EU-EC-10008659387 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blindness unilateral (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (8d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hydrocephalus (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypertension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pupil fixed (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pupils unequal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vomiting (8d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17536 | click or scan EU-EC-10008659364 | | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral artery occlusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic transformation stroke (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery occlusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17537 | click or scan EU-EC-10008659310 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a]) |
| 17538 | click or scan EU-EC-10008657478 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulse absent (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17539 | click or scan EU-EC-10008656740 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Speech disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (1d - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17540 | click or scan EU-EC-10008656483 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blindness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17541 | click or scan EU-EC-10008656475 | | 2021-05-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17542 | click or scan EU-EC-10008656450 | | 2021-05-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17543 | click or scan EU-EC-10008656435 | | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17544 | click or scan EU-EC-10008656416 | | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17545 | click or scan EU-EC-10008656415 | | 2021-05-15 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 17546 | click or scan EU-EC-10008656232 | | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic arteriosclerosis (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral atrophy (n/a - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Lung neoplasm (n/a - Fatal - **Results in Death**), Platelet count abnormal (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17547 | click or scan EU-EC-10008656230 | | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17548 | click or scan EU-EC-10008656214 | | 2021-05-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood fibrinogen increased (n/a - Fatal - **Results in Death**), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17549 | click or scan EU-EC-10008656057 | | 2021-05-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17550 | click or scan EU-EC-10008655729 | | 2021-05-15 | Healthcare Professional | EEA | 65-85 Years | Male | Arterial thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17551 | click or scan EU-EC-10008655717 | | 2021-05-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal distension (0d - Fatal - **Results in Death**), Cardio-respiratory arrest (0d - Fatal - **Results in Death**), Dyschezia (0d - Fatal - **Results in Death**), Dysuria (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17552 | click or scan EU-EC-10008655696 | | 2021-05-15 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17553 | click or scan EU-EC-10008655618 | | 2021-05-15 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17554 | click or scan EU-EC-10008655546 | | 2021-05-15 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Unknown - [n/a - .5mL - Intramuscular]) |
| 17555 | click or scan EU-EC-10008655356 | | 2021-05-15 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 17556 | click or scan EU-EC-10008655345 | | 2021-05-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 17557 | click or scan EU-EC-10008653802 | | 2021-05-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 17558 | click or scan EU-EC-10008653288 | | 2021-05-15 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**), Pallor (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17559 | click or scan EU-EC-10008653005 | | 2021-05-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |
| 17560 | click or scan EU-EC-10008653000 | | 2021-05-15 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17561 | click or scan EU-EC-10008652962 | | 2021-05-15 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Hypertensive crisis (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17562** | click or scan EU-EC-10008654779 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hospitalisation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17563** | click or scan EU-EC-10008654676 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17564** | click or scan EU-EC-10008654537 |  | 2021-05-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17565** | click or scan EU-EC-10008654528 |  | 2021-05-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **17566** | click or scan EU-EC-10008654468 |  | 2021-05-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **17567** | click or scan EU-EC-10008654365 |  | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | Fumbling (n/a - Fatal - **Results in Death**), Mental impairment (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **17568** | click or scan EU-EC-10008654267 |  | 2021-05-14 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **17569** | click or scan EU-EC-10008654158 |  | 2021-05-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - n/a]) |
| **17570** | click or scan EU-EC-10008654076 |  | 2021-05-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Unevaluable event (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17571** | click or scan EU-EC-10008653912 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17572 | click or scan EU-EC-10008653859 |  | 2021-05-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17573 | click or scan EU-EC-10008653846 |  | 2021-05-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hospitalisation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17574 | click or scan EU-EC-10008653844 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17575 | click or scan EU-EC-10008653638 |  | 2021-05-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17576 | click or scan EU-EC-10008653631 |  | 2021-05-14 | Healthcare Professional | Non EEA | Not Specified | Male | Body temperature increased (1d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17577 | click or scan EU-EC-10008653614 |  | 2021-05-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17578 | click or scan EU-EC-10008653597 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17579 | click or scan EU-EC-10008653573 |  | 2021-05-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hospitalisation (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17580 | click or scan EU-EC-10008653571 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17581 | click or scan EU-EC-10008653552 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17582 | click or scan EU-EC-10008653539 | | 2021-05-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17583 | click or scan EU-EC-10008653403 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute cardiac event (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17584 | click or scan EU-EC-10008652692 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17585 | click or scan EU-EC-10008652680 | | 2021-05-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17586 | click or scan EU-EC-10008652464 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17587 | click or scan EU-EC-10008651528 | | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 17588 | click or scan EU-EC-10008650859 | | 2021-05-14 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 17589 | click or scan EU-EC-10008650696 | | 2021-05-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal perforation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17590 | click or scan EU-EC-10008650523 | | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17591 | click or scan EU-EC-10008650402 | | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (0d - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17592 | click or scan EU-EC-10008650207 |  | 2021-05-14 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17593 | click or scan EU-EC-10008650191 |  | 2021-05-14 | Healthcare Professional | EEA | 18-64 Years | Female | Oesophageal varices haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17594 | click or scan EU-EC-10008650021 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Male | Epistaxis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17595 | click or scan EU-EC-10008649982 |  | 2021-05-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Hypopnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17596 | click or scan EU-EC-10008649709 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17597 | click or scan EU-EC-10008649691 |  | 2021-05-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Sudden death (1d - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17598 | click or scan EU-EC-10008649585 |  | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17599 | click or scan EU-EC-10008649580 |  | 2021-05-14 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17600 | click or scan EU-EC-10008649555 |  | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17601 | click or scan EU-EC-10008649537 |  | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [2s - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17602** | click or scan EU-EC-10008649283 | | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17603** | click or scan EU-EC-10008648913 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (11d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Urinary tract infection (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17604** | click or scan EU-EC-10008648659 | | 2021-05-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17605** | click or scan EU-EC-10008648652 | | 2021-05-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17606** | click or scan EU-EC-10008648614 | | 2021-05-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Autopsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling hot (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Impaired work ability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Poor peripheral circulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **17607** | click or scan EU-EC-10008648611 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Clostridium difficile colitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Clostridium test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colitis ischaemic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jugular vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subclavian vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Superficial vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ultrasound Doppler abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **17608** | click or scan EU-EC-10008648605 | | 2021-05-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **17609** | click or scan EU-EC-10008648535 | | 2021-05-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17610 | click or scan EU-EC-10008648359 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Angioplasty (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heparin-induced thrombocytopenia test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunoglobulin therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet factor 4 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombectomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17611 | click or scan EU-EC-10008648342 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17612 | click or scan EU-EC-10008647817 |  | 2021-05-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Back pain (7d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (7d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (7d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (7d - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (7d - Fatal - **Results in Death**, Other Medically Important Condition), Vena cava thrombosis (7d - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17613 | click or scan EU-EC-10008647160 |  | 2021-05-14 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17614 | click or scan EU-EC-10008647140 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17615 | click or scan EU-EC-10008647085 |  | 2021-05-14 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17616 | click or scan EU-EC-10008647056 |  | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Malaise (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17617 | click or scan EU-EC-10008647042 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17618 | click or scan EU-EC-10008647014 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Acute respiratory failure (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17619 | click or scan EU-EC-10008647005 | | 2021-05-14 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17620 | click or scan EU-EC-10008646987 | | 2021-05-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17621 | click or scan EU-EC-10008646982 | | 2021-05-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17622 | click or scan EU-EC-10008646979 | | 2021-05-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17623 | click or scan EU-EC-10008646970 | | 2021-05-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Ascites (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Hot flush (n/a - Not Recovered/Not Resolved - ), Lymphoedema (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17624 | click or scan EU-EC-10008646967 | | 2021-05-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 17625 | click or scan EU-EC-10008646945 | | 2021-05-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17626 | click or scan EU-EC-10008646942 | | 2021-05-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17627 | click or scan EU-EC-10008646941 | | 2021-05-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17628 | click or scan EU-EC-10008646938 | | 2021-05-14 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17629 | click or scan EU-EC-10008646890 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17630 | click or scan EU-EC-10008646479 |  | 2021-05-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 17631 | click or scan EU-EC-10008646476 |  | 2021-05-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17632 | click or scan EU-EC-10008646421 |  | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (4d - Fatal - **Results in Death**, Other Medically Important Condition), Hydrocephalus (4d - Fatal - **Results in Death**, Other Medically Important Condition), Ischaemic stroke (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17633 | click or scan EU-EC-10008646401 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17634 | click or scan EU-EC-10008646322 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17635 | click or scan EU-EC-10008646174 |  | 2021-05-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17636 | click or scan EU-EC-10008646068 |  | 2021-05-14 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17637 | click or scan EU-EC-10008645903 |  | 2021-05-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Dementia (n/a - Not Recovered/Not Resolved - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17638 | click or scan EU-EC-10008645786 |  | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17639 | click or scan EU-EC-10008645671 |  | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Female | Aspiration (n/a - Not Recovered/Not Resolved - ), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17640** | click or scan EU-EC-10008645494 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **17641** | click or scan EU-EC-10008645467 | | 2021-05-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17642** | click or scan EU-EC-10008645314 | | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **17643** | click or scan EU-EC-10008645025 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17644** | click or scan EU-EC-10008644915 | | 2021-05-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17645** | click or scan EU-EC-10008644584 | | 2021-05-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **17646** | click or scan EU-EC-10008644475 | | 2021-05-14 | Healthcare Professional | EEA | 65-85 Years | Female | Anuria (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Hyperlactacidaemia (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **17647** | click or scan EU-EC-10008644255 | | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **17648** | click or scan EU-EC-10008643781 | | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **17649** | click or scan EU-EC-10008643776 | | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **17650** | click or scan EU-EC-10008642653 | | 2021-05-14 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (7d - Fatal - **Results in Death**), Pain (7d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17651** | click or scan EU-EC-10008642550 | | 2021-05-14 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (98d - Fatal - **Results in Death**), Ischaemic stroke (98d - Fatal - **Results in Death**), Pyrexia (98d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **17652** | click or scan EU-EC-10008641993 | | 2021-05-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic valve sclerosis (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coronary artery disease (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Drug ineffective (n/a - Unknown - ), Dysphonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Hyperdynamic left ventricle (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune-mediated lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intentional product use issue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Mitral valve incompetence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (n/a - Unknown - ), Pulmonary fibrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Right atrial dilatation (n/a - Unknown - ), Right ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Therapeutic product effect incomplete (n/a - Unknown - ), Tricuspid valve incompetence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unevaluable event (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), FIRDAPSE [AMIFAMPRIDINE] (S - Myasthenic syndrome - Dose not changed - [154d - 30mg - Oral]) |
| **17653** | click or scan EU-EC-10008641263 | | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood glucose increased (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Dyspnoea (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (1d - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17654** | click or scan EU-EC-10008641202 | | 2021-05-13 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular]) |
| **17655** | click or scan EU-EC-10008641090 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (2d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]) |
| **17656** | click or scan EU-EC-10008640970 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sneezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **17657** | click or scan EU-EC-10008640855 | | 2021-05-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injection site pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17658** | click or scan EU-EC-10008640803 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Confusional state (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Fall (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Head injury (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Pulseless electrical activity (1d - Fatal - **Results in Death**), Skin abrasion (1d - Not Recovered/Not Resolved - ), Ventricular fibrillation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17659 | click or scan EU-EC-10008640531 |  | 2021-05-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17660 | click or scan EU-EC-10008640497 |  | 2021-05-13 | Healthcare Professional | Non EEA | Not Specified | Male | Completed suicide (n/a - Fatal - **Results in Death**), Tinnitus (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17661 | click or scan EU-EC-10008640220 |  | 2021-05-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Traumatic haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17662 | click or scan EU-EC-10008640197 |  | 2021-05-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Petechiae (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17663 | click or scan EU-EC-10008639590 |  | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17664 | click or scan EU-EC-10008639572 |  | 2021-05-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17665 | click or scan EU-EC-10008639128 |  | 2021-05-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17666 | click or scan EU-EC-10008639116 |  | 2021-05-13 | Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17667 | click or scan EU-EC-10008638925 |  | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17668 | click or scan EU-EC-10008638896 |  | 2021-05-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Body temperature increased (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17669 | click or scan EU-EC-10008638819 |  | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17670 | click or scan EU-EC-10008638690 | | 2021-05-13 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Liver contusion (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Vaccination site erythema (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17671 | click or scan EU-EC-10008638329 | | 2021-05-13 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17672 | click or scan EU-EC-10008638304 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bedridden (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Myocardial infarction (1290min - Fatal - **Results in Death**), Pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17673 | click or scan EU-EC-10008637936 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (9d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Dizziness (20d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (20d - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (20d - Unknown - Caused/Prolonged Hospitalisation), Malaise (20d - Unknown - Caused/Prolonged Hospitalisation), Somnolence (20d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17674 | click or scan EU-EC-10008637914 | | 2021-05-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17675 | click or scan EU-EC-10008637885 | | 2021-05-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Gait disturbance (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17676 | click or scan EU-EC-10008637814 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vasculitis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17677 | click or scan EU-EC-10008637278 | | 2021-05-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**), Seizure (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17678 | click or scan EU-EC-10008637192 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Activated partial thromboplastin time prolonged (n/a - Unknown - ), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood fibrinogen decreased (n/a - Unknown - ), Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown - ), Haematemesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematuria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Head injury (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Traumatic haemorrhage (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17679 | click or scan EU-EC-10008637083 | | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17680 | click or scan EU-EC-10008637014 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17681 | click or scan EU-EC-10008636744 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Feeding disorder (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Fluid intake reduced (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperhidrosis (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Life Threatening), Tremor (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (2d - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17682 | click or scan EU-EC-10008636475 | | 2021-05-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Bone pain (n/a - Unknown - ), Fall (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ), Malaise (n/a - Unknown - ), Malaise (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - ), Pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17683 | click or scan EU-EC-10008636459 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute left ventricular failure (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Acute pulmonary oedema (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Acute respiratory failure (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vitamin B12 deficiency (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17684 | click or scan EU-EC-10008636448 | | 2021-05-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17685 | click or scan EU-EC-10008636329 | | 2021-05-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17686 | click or scan EU-EC-10008636305 | | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain injury (10d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (10d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17687 | click or scan EU-EC-10008636300 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 17688 | click or scan EU-EC-10008636156 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (10d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Hyperhidrosis (10d - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (10d - Not Recovered/Not Resolved - Other Medically Important Condition), Tachypnoea (10d - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17689 | click or scan EU-EC-10008636150 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17690 | click or scan EU-EC-10008636039 | | 2021-05-13 | Healthcare Professional | EEA | 18-64 Years | Female | Oesophageal varices haemorrhage (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17691 | click or scan EU-EC-10008635995 | | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Sinus tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Supraventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17692 | click or scan EU-EC-10008635942 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 17693 | click or scan EU-EC-10008635630 | | 2021-05-13 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17694 | click or scan EU-EC-10008635333 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiopulmonary failure (4d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Secretion discharge (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17695 | click or scan EU-EC-10008634353 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17696 | click or scan EU-EC-10008634343 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (4d - Fatal - **Results in Death**), Cardiac failure (4d - Fatal - **Results in Death**), Fatigue (4d - Fatal - **Results in Death**), Fluid retention (4d - Fatal - **Results in Death**), Intensive care (4d - Fatal - **Results in Death**), Peripheral swelling (4d - Fatal - **Results in Death**), Pulmonary oedema (4d - Fatal - **Results in Death**), Snoring (4d - Fatal - **Results in Death**), Swelling (4d - Fatal - **Results in Death**), Urinary retention (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17697 | click or scan EU-EC-10008634042 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune system disorder (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17698 | click or scan EU-EC-10008634035 | | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17699 | click or scan EU-EC-10008633302 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17700 | click or scan EU-EC-10008633148 | | 2021-05-13 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17701 | click or scan EU-EC-10008633114 | | 2021-05-13 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17702 | click or scan EU-EC-10008633048 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Snoring (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17703 | click or scan EU-EC-10008632885 | | 2021-05-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17704 | click or scan EU-EC-10008632083 | | 2021-05-13 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 17705 | click or scan EU-EC-10008631978 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17706 | click or scan EU-EC-10008631696 | | 2021-05-13 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intraocular]) |
| 17707 | click or scan EU-EC-10008631693 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Female | Chest pain (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Pulmonary embolism (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17708 | click or scan EU-EC-10008631556 | | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Incorrect route of product administration (n/a - Recovered/Resolved - ), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous - More in ICSR]) |
| 17709 | click or scan EU-EC-10008631468 | | 2021-05-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17710 | click or scan EU-EC-10008631466 | | 2021-05-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (1d - Fatal - **Results in Death**), Condition aggravated (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17711 | click or scan EU-EC-10008631409 | | 2021-05-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Overdose (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17712 | click or scan EU-EC-10008629771 | | 2021-05-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17713 | click or scan EU-EC-10008629609 | | 2021-05-13 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17714 | click or scan EU-EC-10008631320 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic stroke (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17715 | click or scan EU-EC-10008630113 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (1d - Fatal - **Results in Death**), Cyanosis (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17716 | click or scan EU-EC-10008630051 | | 2021-05-12 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17717 | click or scan EU-EC-10008629493 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 17718 | click or scan EU-EC-10008628990 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17719 | click or scan EU-EC-10008628451 | | 2021-05-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17720 | click or scan EU-EC-10008628166 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cholestasis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperbilirubinaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Microangiopathic haemolytic anaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic microangiopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17721 | click or scan EU-EC-10008628148 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17722 | click or scan EU-EC-10008627856 | | 2021-05-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17723 | click or scan EU-EC-10008627363 | | 2021-05-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17724 | click or scan EU-EC-10008627140 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blindness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17725 | click or scan EU-EC-10008627135 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17726 | click or scan EU-EC-10008627102 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening), Drooling (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Fatal - **Results in Death**, Life Threatening), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Nausea (n/a - Fatal - **Results in Death**, Life Threatening), Reduction of increased intracranial pressure (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17727 | click or scan EU-EC-10008626974 | | 2021-05-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal mass (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17728 | click or scan EU-EC-10008626973 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17729 | click or scan EU-EC-10008626890 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal exploration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17730 | click or scan EU-EC-10008626887 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17731 | click or scan EU-EC-10008626732 | | 2021-05-12 | Healthcare Professional | EEA | 18-64 Years | Female | Agitation (n/a - Not Recovered/Not Resolved - ), Apathy (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Concomitant disease aggravated (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Dysphagia (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Haematoma (n/a - Unknown - ), Head titubation (n/a - Not Recovered/Not Resolved - ), Memory impairment (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**), Tremor (n/a - Not Recovered/Not Resolved - ), Urinary incontinence (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17732 | click or scan EU-EC-10008626331 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Incomplete course of vaccination (1d - Fatal - **Results in Death**), Syncope (12d - Fatal - **Results in Death**), Urinary tract infection (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17733 | click or scan EU-EC-10008625889 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17734 | click or scan EU-EC-10008625852 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17735 | click or scan EU-EC-10008625850 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| 17736 | click or scan EU-EC-10008625839 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| 17737 | click or scan EU-EC-10008625838 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Atrioventricular block (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Psychomotor skills impaired (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17738 | click or scan EU-EC-10008625807 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |
| 17739 | click or scan EU-EC-10008625803 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [MIRTAZAPINE] (S - Major depression - Not applicable - [5d - 15mg - Oral]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17740 | click or scan EU-EC-10008625798 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 17741 | click or scan EU-EC-10008625713 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [50d - 1 {DF} - Intramuscular]) |
| 17742 | click or scan EU-EC-10008625704 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [16d - 2 {DF} - Intramuscular]) |
| 17743 | click or scan EU-EC-10008625703 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17744 | click or scan EU-EC-10008625702 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]) |
| 17745 | click or scan EU-EC-10008625699 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 17746 | click or scan EU-EC-10008625698 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Subarachnoid haemorrhage (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1 {DF} - Intramuscular]), ZIRABEV [BEVACIZUMAB] (S - Adenocarcinoma of colon - Not applicable - [190d - 5mg/kg - Intravenous drip]) |
| 17747 | click or scan EU-EC-10008624901 | | 2021-05-12 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17748 | click or scan EU-EC-10008624761 | | 2021-05-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17749 | click or scan EU-EC-10008624462 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17750 | click or scan EU-EC-10008624461 | | 2021-05-12 | Healthcare Professional | EEA | Not Specified | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17751 | click or scan EU-EC-10008624316 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Female | Intracardiac thrombus (14d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17752 | click or scan EU-EC-10008624050 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Peripheral coldness (1d - Unknown - ), Pulse absent (1d - Unknown - ), Respiratory arrest (1d - Unknown - ), Trismus (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17753 | click or scan EU-EC-10008623966 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (1d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dizziness (1d - Unknown - Other Medically Important Condition), Muscular weakness (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17754 | click or scan EU-EC-10008623831 | | 2021-05-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Unknown - ), Head discomfort (n/a - Unknown - ), Monoparesis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17755 | click or scan EU-EC-10008623775 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17756 | click or scan EU-EC-10008623509 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 17757 | click or scan EU-EC-10008623405 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17758 | click or scan EU-EC-10008623254 | | 2021-05-12 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Procedural pneumothorax (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - ), Venous thrombosis limb (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17759 | click or scan EU-EC-10008623252 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (20d - Fatal - **Results in Death**), Cough (20d - Fatal - **Results in Death**), Epistaxis (20d - Fatal - **Results in Death**), Lung infiltration (20d - Fatal - **Results in Death**), Nasopharyngitis (20d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17760 | click or scan EU-EC-10008623248 | | 2021-05-12 | Healthcare Professional | EEA | 18-64 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haematoma (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17761 | click or scan EU-EC-10008623240 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Cough (11d - Fatal - **Results in Death**), Dyspnoea (11d - Fatal - **Results in Death**), Pulmonary embolism (11d - Fatal - **Results in Death**), Somnolence (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17762 | click or scan EU-EC-10008623080 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17763 | click or scan EU-EC-10008623077 | | 2021-05-12 | Healthcare Professional | EEA | 18-64 Years | Male | Guillain-Barre syndrome (3wk - Fatal - **Results in Death**), Pulmonary embolism (3wk - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17764 | click or scan EU-EC-10008622978 | | 2021-05-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17765 | click or scan EU-EC-10008622660 | | 2021-05-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain injury (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Lip discolouration (n/a - Recovered/Resolved - ), Pulse abnormal (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17766 | click or scan EU-EC-10008622612 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17767 | click or scan EU-EC-10008621888 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Female | Arterial occlusive disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden cardiac death (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17768 | click or scan EU-EC-10008621864 | | 2021-05-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 17769 | click or scan EU-EC-10008621863 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17770 | click or scan EU-EC-10008621777 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17771 | click or scan EU-EC-10008621581 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17772 | click or scan EU-EC-10008621539 | | 2021-05-12 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17773 | click or scan EU-EC-10008621165 | | 2021-05-12 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17774 | click or scan EU-EC-10008620940 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17775 | click or scan EU-EC-10008620575 | | 2021-05-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [OXYCODONE HYDROCHLORIDE] (S - Arthralgia - Dose increased - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (S - Arthralgia - Drug withdrawn - [n/a - n/a - n/a]) |
| 17776 | click or scan EU-EC-10008620033 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17777 | click or scan EU-EC-10008619808 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17778 | click or scan EU-EC-10008619705 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Life support (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17779 | click or scan EU-EC-10008619584 | | 2021-05-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cognitive disorder (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ), Hallucination (n/a - Unknown - ), Headache (n/a - Unknown - ), Monoparesis (n/a - Unknown - ), Neck pain (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17780 | click or scan EU-EC-10008619214 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (15d - Fatal - **Results in Death**), Carotid pulse abnormal (n/a - Unknown - Other Medically Important Condition), Dysarthria (15d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (15d - Recovered/Resolved - Other Medically Important Condition), Pupil fixed (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17781 | click or scan EU-EC-10008618940 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17782 | click or scan EU-EC-10008618802 | | 2021-05-12 | Healthcare Professional | EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 17783 | click or scan EU-EC-10008618627 | | 2021-05-12 | Healthcare Professional | EEA | Not Specified | Female | Abdominal pain (n/a - Unknown - ), Cardiac disorder (n/a - Unknown - ), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Embolism (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17784 | click or scan EU-EC-10008618526 | | 2021-05-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Choking (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Eating disorder (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Insomnia (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Salivary hypersecretion (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Secretion discharge (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17785 | click or scan EU-EC-10008618517 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 17786 | click or scan EU-EC-10008618418 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Hypoaesthesia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17787 | click or scan EU-EC-10008618356 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17788 | click or scan EU-EC-10008618222 | | 2021-05-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17789 | click or scan EU-EC-10008617204 | | 2021-05-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17790 | click or scan EU-EC-10008617199 | | 2021-05-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17791 | click or scan EU-EC-10008617181 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Foaming at mouth (n/a - Unknown - Other Medically Important Condition), Gaze palsy (n/a - Unknown - Other Medically Important Condition), Posture abnormal (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Seizure like phenomena (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17792 | click or scan EU-EC-10008617176 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic kidney disease (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular tachycardia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17793 | click or scan EU-EC-10008617122 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17794 | click or scan EU-EC-10008617109 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain herniation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningioma benign (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thalamic infarction (1mo - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17795 | click or scan EU-EC-10008617062 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute interstitial pneumonitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Bronchiectasis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (24d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Nodule (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17796 | click or scan EU-EC-10008617029 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (1d - Unknown - Other Medically Important Condition), Condition aggravated (1d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17797 | click or scan EU-EC-10008616817 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17798** | click or scan EU-EC-10008616800 | | 2021-05-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Transverse sinus thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17799** | click or scan EU-EC-10008616798 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebellar haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17800** | click or scan EU-EC-10008616791 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17801** | click or scan EU-EC-10008616748 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **17802** | click or scan EU-EC-10008616707 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - Other Medically Important Condition), Injection site erythema (n/a - Unknown - ), Injection site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17803** | click or scan EU-EC-10008616699 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17804** | click or scan EU-EC-10008616665 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspepsia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17805** | click or scan EU-EC-10008616573 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17806** | click or scan EU-EC-10008616569 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17807** | click or scan EU-EC-10008616518 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17808** | click or scan EU-EC-10008616483 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pneumocystis jirovecii pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **17809** | click or scan EU-EC-10008616394 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17810** | click or scan EU-EC-10008616371 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17811** | click or scan EU-EC-10008616290 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **17812** | click or scan EU-EC-10008616239 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17813** | click or scan EU-EC-10008616014 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17814** | click or scan EU-EC-10008616008 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17815** | click or scan EU-EC-10008616006 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cachexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17816** | click or scan EU-EC-10008616004 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **17817** | click or scan EU-EC-10008615999 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Lethargy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **17818** | click or scan EU-EC-10008615996 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Female | Cachexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **17819** | click or scan EU-EC-10008615969 |  | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17820** | click or scan EU-EC-10008615953 |  | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - ), Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17821** | click or scan EU-EC-10008615266 |  | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Injury (1d - Fatal - **Results in Death**), Road traffic accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17822** | click or scan EU-EC-10008614782 |  | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Female | Breath sounds abnormal (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **17823** | click or scan EU-EC-10008614531 |  | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asphyxia (1d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dysphagia (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **17824** | click or scan EU-EC-10008613966 |  | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17825** | click or scan EU-EC-10008613795 |  | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Dysphonia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **17826** | click or scan EU-EC-10008613748 |  | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Haemorrhagic disorder (n/a - Fatal - **Results in Death**), Livedo reticularis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **17827** | click or scan EU-EC-10008613743 |  | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **17828** | click or scan EU-EC-10008613741 |  | 2021-05-11 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Gait inability (n/a - Unknown - Other Medically Important Condition), Hypersomnia (n/a - Unknown - Other Medically Important Condition), Incontinence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17829** | click or scan EU-EC-10008613375 | | 2021-05-11 | Non Healthcare Professional | EEA | Not Specified | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **17830** | click or scan EU-EC-10008613085 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | Blood lactic acid increased (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **17831** | click or scan EU-EC-10008613030 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **17832** | click or scan EU-EC-10008612921 | | 2021-05-11 | Healthcare Professional | Non EEA | Not Specified | Male | Death neonatal (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Premature baby (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental]) |
| **17833** | click or scan EU-EC-10008612890 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17834** | click or scan EU-EC-10008612706 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**), Agonal rhythm (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Sinus bradycardia (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**), Therapeutic hypothermia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17835** | click or scan EU-EC-10008611744 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (15d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Initial insomnia (n/a - Unknown - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Weight bearing difficulty (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **17836** | click or scan EU-EC-10008611685 | | 2021-05-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17837** | click or scan EU-EC-10008611639 | | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17838** | click or scan EU-EC-10008611638 | | 2021-05-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac discomfort (n/a - Unknown - ), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Performance status decreased (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17839 | click or scan EU-EC-10008611632 |  | 2021-05-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17840 | click or scan EU-EC-10008611631 |  | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17841 | click or scan EU-EC-10008611629 |  | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17842 | click or scan EU-EC-10008611587 |  | 2021-05-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17843 | click or scan EU-EC-10008611563 |  | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17844 | click or scan EU-EC-10008611562 |  | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Influenza (n/a - Not Recovered/Not Resolved - ), Right ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17845 | click or scan EU-EC-10008611561 |  | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17846 | click or scan EU-EC-10008611316 |  | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17847 | click or scan EU-EC-10008611294 |  | 2021-05-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17848 | click or scan EU-EC-10008611201 |  | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17849 | click or scan EU-EC-10008611120 |  | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory distress (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17850 | click or scan EU-EC-10008611117 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 17851 | click or scan EU-EC-10008611097 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 17852 | click or scan EU-EC-10008611060 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| 17853 | click or scan EU-EC-10008611002 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17854 | click or scan EU-EC-10008610997 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| 17855 | click or scan EU-EC-10008610905 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 17856 | click or scan EU-EC-10008610874 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 17857 | click or scan EU-EC-10008610864 | | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Eye haemorrhage (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 2{DF} - Intramuscular]) |
| 17858 | click or scan EU-EC-10008610837 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasms (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17859 | click or scan EU-EC-10008610172 | | 2021-05-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17860 | click or scan EU-EC-10008610166 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apnoeic attack (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Obstructive airways disorder (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 17861 | click or scan EU-EC-10008610162 | | 2021-05-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Autism spectrum disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17862 | click or scan EU-EC-10008610058 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Haemolysis (1d - Fatal - **Results in Death**), Jaundice (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17863 | click or scan EU-EC-10008609871 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| 17864 | click or scan EU-EC-10008609831 | | 2021-05-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17865 | click or scan EU-EC-10008609751 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Therapeutic hypothermia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17866 | click or scan EU-EC-10008609639 | | 2021-05-11 | Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), [ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID PH. EUR.] (S - Antiphospholipid syndrome - n/a - [n/a - 100mg - Oral]) |
| 17867 | click or scan EU-EC-10008609604 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute coronary syndrome (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17868 | click or scan EU-EC-10008609549 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17869 | click or scan EU-EC-10008609118 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Malaise (1d - Unknown - Other Medically Important Condition), Pyrexia (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17870 | click or scan EU-EC-10008608922 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17871 | click or scan EU-EC-10008608509 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17872 | click or scan EU-EC-10008608404 | | 2021-05-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17873 | click or scan EU-EC-10008608306 | | 2021-05-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 17874 | click or scan EU-EC-10008608250 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17875 | click or scan EU-EC-10008608239 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17876 | click or scan EU-EC-10008608224 | | 2021-05-11 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17877 | click or scan EU-EC-10008608211 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17878 | click or scan EU-EC-10008608196 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17879 | click or scan EU-EC-10008608178 | | 2021-05-11 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17880** | click or scan EU-EC-10008608121 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Fatal - **Results in Death**), Blood pressure immeasurable (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Illness (n/a - Fatal - **Results in Death**), Peripheral arterial occlusive disease (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory rate increased (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Sinus tachycardia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **17881** | click or scan EU-EC-10008607931 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Thrombosis (46d - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **17882** | click or scan EU-EC-10008607887 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac disorder (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17883** | click or scan EU-EC-10008607883 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Hyperkalaemia (n/a - Fatal - **Results in Death**), Low density lipoprotein increased (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Transaminases increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **17884** | click or scan EU-EC-10008607832 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17885** | click or scan EU-EC-10008607739 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (16d - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Electrolyte imbalance (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (16d - Fatal - **Results in Death**, Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17886** | click or scan EU-EC-10008607591 | | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Asthenia (n/a - Unknown - ), COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - ), Oxygen saturation decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), PCO2 abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sudden hearing loss (n/a - Unknown - Other Medically Important Condition), Tinnitus (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17887** | click or scan EU-EC-10008607581 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17888 | click or scan EU-EC-10008607513 | | 2021-05-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anxiety (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Choking (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Insomnia (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Salivary hypersecretion (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Secretion discharge (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Tracheal obstruction (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17889 | click or scan EU-EC-10008607488 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17890 | click or scan EU-EC-10008607170 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17891 | click or scan EU-EC-10008607060 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17892 | click or scan EU-EC-10008606922 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening), Rash (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17893 | click or scan EU-EC-10008606904 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hospitalisation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17894 | click or scan EU-EC-10008606896 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 17895 | click or scan EU-EC-10008606819 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]), [ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]) |
| 17896 | click or scan EU-EC-10008606809 | | 2021-05-11 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17897 | click or scan EU-EC-10008606784 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Female | Cachexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17898 | click or scan EU-EC-10008606781 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17899 | click or scan EU-EC-10008606764 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apnoea (n/a - Unknown - Other Medically Important Condition), Blood alcohol increased (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Haemorrhage (n/a - Unknown - Other Medically Important Condition), Laryngeal haemorrhage (n/a - Unknown - Other Medically Important Condition), Pharyngeal haemorrhage (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17900 | click or scan EU-EC-10008606425 | | 2021-05-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia bacterial (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17901 | click or scan EU-EC-10008606259 | | 2021-05-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 17902 | click or scan EU-EC-10008606170 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17903 | click or scan EU-EC-10008606160 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (5d - Fatal - **Results in Death**), Diarrhoea (5d - Fatal - **Results in Death**), Fatigue (5d - Fatal - **Results in Death**), Haematemesis (0d - Fatal - **Results in Death**), Pain of skin (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**), Visual acuity reduced (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17904 | click or scan EU-EC-10008606069 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17905 | click or scan EU-EC-10008606035 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17906 | click or scan EU-EC-10008605953 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), COVID-19 (54d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (54d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17907 | click or scan EU-EC-10008605944 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17908 | click or scan EU-EC-10008605905 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17909 | click or scan EU-EC-10008605897 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17910 | click or scan EU-EC-10008605785 | | 2021-05-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Flushing (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Vaccination complication (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17911 | click or scan EU-EC-10008605758 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17912 | click or scan EU-EC-10008605757 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17913 | click or scan EU-EC-10008605713 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (4d - Unknown - Other Medically Important Condition), Aspiration (4d - Fatal - **Results in Death**), Cough (4d - Unknown - Other Medically Important Condition), Myocardial infarction (4d - Fatal - **Results in Death**), Vomiting (4d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17914 | click or scan EU-EC-10008605685 | | 2021-05-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17915 | click or scan EU-EC-10008605587 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17916 | click or scan EU-EC-10008605512 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17917 | click or scan EU-EC-10008605467 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17918 | click or scan EU-EC-10008605422 | | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Dysphoria (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 17919 | click or scan EU-EC-10008605406 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17920 | click or scan EU-EC-10008605393 | | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17921 | click or scan EU-EC-10008605380 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17922 | click or scan EU-EC-10008605355 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17923 | click or scan EU-EC-10008605343 | | 2021-05-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 17924 | click or scan EU-EC-10008605320 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17925 | click or scan EU-EC-10008605284 | | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1041min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17926 | click or scan EU-EC-10008605229 | | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17927 | click or scan EU-EC-10008605114 |  | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17928 | click or scan EU-EC-10008605033 |  | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 17929 | click or scan EU-EC-10008604953 |  | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17930 | click or scan EU-EC-10008604826 |  | 2021-05-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Lip swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17931 | click or scan EU-EC-10008604795 |  | 2021-05-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17932 | click or scan EU-EC-10008604700 |  | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17933 | click or scan EU-EC-10008604696 |  | 2021-05-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17934 | click or scan EU-EC-10008603771 |  | 2021-05-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Respiratory failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17935 | click or scan EU-EC-10008603027 |  | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17936 | click or scan EU-EC-10008602942 |  | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17937** | click or scan EU-EC-10008602861 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17938** | click or scan EU-EC-10008602857 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Peripheral embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17939** | click or scan EU-EC-10008602675 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17940** | click or scan EU-EC-10008602619 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17941** | click or scan EU-EC-10008602458 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pollakiuria (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **17942** | click or scan EU-EC-10008602437 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **17943** | click or scan EU-EC-10008602243 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **17944** | click or scan EU-EC-10008602123 | | 2021-05-10 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **17945** | click or scan EU-EC-10008602045 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Discomfort (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Skin haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - n/a]) |
| **17946** | click or scan EU-EC-10008602032 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **17947** | click or scan EU-EC-10008601924 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17948 | click or scan EU-EC-10008601915 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Right ventricular dilatation (n/a - Unknown - Caused/Prolonged Hospitalisation), Right ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17949 | click or scan EU-EC-10008601862 | | 2021-05-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17950 | click or scan EU-EC-10008601253 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Contusion (n/a - Unknown - ), Fall (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Unknown - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal function test abnormal (n/a - Unknown - ), Urinary tract infection (n/a - Unknown - ), Wound (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 17951 | click or scan EU-EC-10008600987 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17952 | click or scan EU-EC-10008600754 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Food refusal (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 17953 | click or scan EU-EC-10008600638 | | 2021-05-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 17954 | click or scan EU-EC-10008600554 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 17955 | click or scan EU-EC-10008600439 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 17956 | click or scan EU-EC-10008600383 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bradycardia (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (2d - Unknown - Caused/Prolonged Hospitalisation), Fall (2d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (2d - Unknown - Caused/Prolonged Hospitalisation), Hypotension (2d - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus node dysfunction (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17957 | click or scan EU-EC-10008600313 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17958 | click or scan EU-EC-10008600247 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17959 | click or scan EU-EC-10008600190 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Injection site pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17960 | click or scan EU-EC-10008600156 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 17961 | click or scan EU-EC-10008599860 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fracture (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17962 | click or scan EU-EC-10008599769 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Respiratory arrest (7d - Fatal - **Results in Death**), Respiratory disorder (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17963 | click or scan EU-EC-10008599698 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17964 | click or scan EU-EC-10008599684 | | 2021-05-10 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 17965 | click or scan EU-EC-10008599491 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute cardiac event (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17966 | click or scan EU-EC-10008599480 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17967 | click or scan EU-EC-10008599469 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Incomplete course of vaccination (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17968 | click or scan EU-EC-10008599281 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 17969 | click or scan EU-EC-10008599114 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), XARELTO [RIVAROXABAN] (S - Atrial fibrillation - Not applicable - [n/a - 20mg - Oral]) |
| 17970 | click or scan EU-EC-10008599095 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 17971 | click or scan EU-EC-10008599029 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 1 {DF} - Intramuscular]) |
| 17972 | click or scan EU-EC-10008599013 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 17973 | click or scan EU-EC-10008599012 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 17974 | click or scan EU-EC-10008598888 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 17975 | click or scan EU-EC-10008598870 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 17976 | click or scan EU-EC-10008598869 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]), [CYAMEMAZINE] (S - n/a - n/a - [n/a - 10mg - n/a]), [DOMPERIDONE] (S - n/a - n/a - [n/a - 30mg - n/a]), [ESCITALOPRAM] (S - n/a - n/a - [n/a - 10mg - n/a]) |
| 17977 | click or scan EU-EC-10008598864 | | 2021-05-10 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **17978** | click or scan EU-EC-10008598861 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Carotid artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **17979** | click or scan EU-EC-10008598844 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **17980** | click or scan EU-EC-10008598281 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17981** | click or scan EU-EC-10008598279 | | 2021-05-10 | Non Healthcare Professional | EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17982** | click or scan EU-EC-10008598277 | | 2021-05-10 | Non Healthcare Professional | EEA | Not Specified | Female | Hepatitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17983** | click or scan EU-EC-10008598254 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17984** | click or scan EU-EC-10008598242 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17985** | click or scan EU-EC-10008597196 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **17986** | click or scan EU-EC-10008596916 | | 2021-05-10 | Healthcare Professional | EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **17987** | click or scan EU-EC-10008596760 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (2d - Fatal - **Results in Death**), Haemoptysis (2d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 17988 | click or scan EU-EC-10008596611 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial flutter (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrioventricular block (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood calcium decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Supraventricular extrasystoles (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17989 | click or scan EU-EC-10008596566 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17990 | click or scan EU-EC-10008596477 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17991 | click or scan EU-EC-10008596263 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 17992 | click or scan EU-EC-10008596247 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Bacteraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Oliguria (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17993 | click or scan EU-EC-10008596239 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (7d - Fatal - **Results in Death**), Diarrhoea (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17994 | click or scan EU-EC-10008596189 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 17995 | click or scan EU-EC-10008596083 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 17996 | click or scan EU-EC-10008596044 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17997 | click or scan EU-EC-10008596019 | | 2021-05-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 17998 | click or scan EU-EC-10008595944 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 17999 | click or scan EU-EC-10008595943 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (12d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18000 | click or scan EU-EC-10008595926 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (1d - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18001 | click or scan EU-EC-10008595857 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Balance disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Essential hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hip fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malnutrition (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), X-ray of pelvis and hip abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18002 | click or scan EU-EC-10008595849 | | 2021-05-10 | Healthcare Professional | EEA | 18-64 Years | Female | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18003 | click or scan EU-EC-10008595845 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - ), Cough (6d - Unknown - ), Death (1d - Fatal - **Results in Death**), Dyspnoea (6d - Unknown - ), Headache (6d - Unknown - ), Oropharyngeal pain (6d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18004 | click or scan EU-EC-10008595617 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18005 | click or scan EU-EC-10008595427 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Carotid artery dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18006 | click or scan EU-EC-10008595313 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18007 | click or scan EU-EC-10008595312 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18008 | click or scan EU-EC-10008595255 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Nausea (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18009 | click or scan EU-EC-10008595210 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18010 | click or scan EU-EC-10008595139 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic hyperosmolar coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18011 | click or scan EU-EC-10008595137 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18012 | click or scan EU-EC-10008594939 | | 2021-05-10 | Healthcare Professional | EEA | Not Specified | Male | Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 18013 | click or scan EU-EC-10008594906 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyramidal tract syndrome (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18014 | click or scan EU-EC-10008594830 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18015 | click or scan EU-EC-10008594773 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Chest pain (n/a - Fatal - **Results in Death**, Life Threatening), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening), Head injury (n/a - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18016 | click or scan EU-EC-10008594771 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18017 | click or scan EU-EC-10008594761 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18018 | click or scan EU-EC-10008594652 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18019 | click or scan EU-EC-10008594583 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18020 | click or scan EU-EC-10008594515 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hospitalisation (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18021 | click or scan EU-EC-10008594350 | | 2021-05-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18022 | click or scan EU-EC-10008594187 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18023 | click or scan EU-EC-10008593839 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18024 | click or scan EU-EC-10008593805 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18025 | click or scan EU-EC-10008593580 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 18026 | click or scan EU-EC-10008593543 | | 2021-05-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18027 | click or scan EU-EC-10008593532 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Chest discomfort (n/a - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18028 | click or scan EU-EC-10008593192 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Organ failure (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18029 | click or scan EU-EC-10008593185 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18030 | click or scan EU-EC-10008593143 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18031 | click or scan EU-EC-10008593142 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18032 | click or scan EU-EC-10008593084 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Clostridium difficile colitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Colitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18033 | click or scan EU-EC-10008593004 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anxiety (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18034 | click or scan EU-EC-10008593003 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Hospitalisation (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18035 | click or scan EU-EC-10008592873 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disease recurrence (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18036 | click or scan EU-EC-10008592823 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18037 | click or scan EU-EC-10008592745 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Male | Anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18038** | click or scan EU-EC-10008592744 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Streptococcal sepsis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18039** | click or scan EU-EC-10008592696 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Decreased appetite (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Oligodipsia (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18040** | click or scan EU-EC-10008592618 | | 2021-05-10 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Tumour thrombosis (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18041** | click or scan EU-EC-10008592577 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18042** | click or scan EU-EC-10008592452 | | 2021-05-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Heart rate decreased (3d - Fatal - **Results in Death**), Hypotension (3d - Fatal - **Results in Death**), Respiratory disorder (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18043** | click or scan EU-EC-10008592252 | | 2021-05-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18044** | click or scan EU-EC-10008592195 | | 2021-05-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Peripheral embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **18045** | click or scan EU-EC-10008591872 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - n/a - n/a]) |
| **18046** | click or scan EU-EC-10008591840 | | 2021-05-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18047** | click or scan EU-EC-10008591671 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18048** | click or scan EU-EC-10008591642 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18049** | click or scan EU-EC-10008591476 | | 2021-05-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **18050** | click or scan EU-EC-10008591215 | | 2021-05-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Hepatic failure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (17d - Unknown - ), Renal failure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18051** | click or scan EU-EC-10008590887 | | 2021-05-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18052** | click or scan EU-EC-10008590705 | | 2021-05-10 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18053** | click or scan EU-EC-10008588856 | | 2021-05-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18054** | click or scan EU-EC-10008588565 | | 2021-05-08 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericardial haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18055** | click or scan<br>EU-EC-10008588564 | | 2021-05-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diverticulitis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nausea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Photophobia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Portal vein phlebitis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Portal vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18056** | click or scan<br>EU-EC-10008588553 | | 2021-05-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain herniation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Diabetes insipidus (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18057** | click or scan<br>EU-EC-10008588166 | | 2021-05-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem stroke (9d - Fatal - **Results in Death**), Circulatory collapse (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18058** | click or scan<br>EU-EC-10008588124 | | 2021-05-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Biliary sepsis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Jaundice (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Polychromasia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18059** | click or scan<br>EU-EC-10008588108 | | 2021-05-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Delirium (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypothermia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18060 | click or scan EU-EC-10008587715 | | 2021-05-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - 1 {DF} - n/a]) |
| 18061 | click or scan EU-EC-10008586090 | | 2021-05-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Circulatory collapse (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Myocardial strain imaging (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Pain in extremity (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulseless electrical activity (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18062 | click or scan EU-EC-10008585829 | | 2021-05-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pancreatitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 18063 | click or scan EU-EC-10008584620 | | 2021-05-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Recovering/Resolving - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 18064 | click or scan EU-EC-10008581201 | | 2021-05-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 18065 | click or scan EU-EC-10008580376 | | 2021-05-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Vena cava thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18066 | click or scan EU-EC-10008580373 | | 2021-05-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (3d - Recovered/Resolved - **Results in Death**), Acute kidney injury (n/a - Not Recovered/Not Resolved - **Results in Death**), Ascites (n/a - Unknown - **Results in Death**), Asthenia (n/a - Unknown - **Results in Death**), Cholelithiasis (n/a - Unknown - **Results in Death**), Circulatory collapse (n/a - Unknown - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Diabetic coma (n/a - Not Recovered/Not Resolved - **Results in Death**), Diarrhoea (n/a - Recovered/Resolved - **Results in Death**), Dysgeusia (n/a - Recovered/Resolved - **Results in Death**), Dysphagia (n/a - Unknown - **Results in Death**), Electrocardiogram ST segment elevation (n/a - Recovered/Resolved - **Results in Death**), Hyperglycaemia (n/a - Not Recovered/Not Resolved - **Results in Death**), Hyperkalaemia (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypoglycaemia (n/a - Not Recovered/Not Resolved - **Results in Death**), Lethargy (n/a - Unknown - **Results in Death**), Myocardial ischaemia (3d - Fatal - **Results in Death**), Pancreatitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Peripancreatic fluid collection (n/a - Unknown - **Results in Death**), Polyuria (n/a - Recovering/Resolving - **Results in Death**), Renal impairment (n/a - Not Recovered/Not Resolved - **Results in Death**), Sluggishness (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18067 | click or scan EU-EC-10008580195 | | 2021-05-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18068 | click or scan EU-EC-10008578029 | | 2021-05-08 | Healthcare Professional | EEA | More than 85 Years | Female | Dehydration (n/a - Fatal - **Results in Death**, Life Threatening), Diarrhoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18069 | click or scan EU-EC-10008577835 | | 2021-05-08 | Healthcare Professional | EEA | 65-85 Years | Male | Dizziness (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18070 | click or scan EU-EC-10008577649 | | 2021-05-08 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18071 | click or scan EU-EC-10008577648 | | 2021-05-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurologic neglect syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18072 | click or scan EU-EC-10008577574 | | 2021-05-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18073 | click or scan EU-EC-10008577532 | | 2021-05-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18074 | click or scan EU-EC-10008577525 | | 2021-05-08 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypophagia (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18075 | click or scan EU-EC-10008577389 | | 2021-05-08 | Healthcare Professional | EEA | More than 85 Years | Female | Vomiting (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18076 | click or scan EU-EC-10008577079 | | 2021-05-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18077 | click or scan EU-EC-10008577065 | | 2021-05-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18078 | click or scan EU-EC-10008576827 | | 2021-05-08 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18079 | click or scan EU-EC-10008575109 | | 2021-05-08 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (5d - Fatal - **Results in Death**), Infarction (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18080 | click or scan EU-EC-10008574983 | | 2021-05-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pyrexia (15d - Fatal - **Results in Death**), Respiratory failure (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular]) |
| 18081 | click or scan EU-EC-10008574740 | | 2021-05-08 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18082 | click or scan EU-EC-10008574529 | | 2021-05-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18083 | click or scan EU-EC-10008576521 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18084 | click or scan EU-EC-10008576518 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18085 | click or scan EU-EC-10008576517 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18086 | click or scan EU-EC-10008576516 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Microangiopathic haemolytic anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18087 | click or scan EU-EC-10008576509 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18088 | click or scan EU-EC-10008576446 |  | 2021-05-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aphasia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endocarditis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperthermia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Joint range of motion decreased (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Osteomyelitis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pseudohyponatraemia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic embolus (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcal infection (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxic encephalopathy (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18089 | click or scan EU-EC-10008576404 |  | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18090 | click or scan EU-EC-10008576401 |  | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18091 | click or scan EU-EC-10008576154 |  | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (13d - Unknown - ), Pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18092 | click or scan EU-EC-10008576031 |  | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18093 | click or scan EU-EC-10008576026 |  | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Anaphylactoid reaction (n/a - Fatal - **Results in Death**), Brain injury (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 18094 | click or scan EU-EC-10008575950 |  | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 18095 | click or scan EU-EC-10008575927 |  | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Guillain-Barre syndrome (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18096** | click or scan EU-EC-10008575891 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18097** | click or scan EU-EC-10008575844 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral artery thrombosis (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **18098** | click or scan EU-EC-10008575839 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **18099** | click or scan EU-EC-10008575819 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **18100** | click or scan EU-EC-10008575753 | | 2021-05-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Blood glucose increased (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Illness (n/a - Unknown - ), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ), Weight decreased (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18101** | click or scan EU-EC-10008575426 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **18102** | click or scan EU-EC-10008575424 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **18103** | click or scan EU-EC-10008575260 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **18104** | click or scan EU-EC-10008575235 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac output decreased (n/a - Unknown - ), Hypokinesia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18105** | click or scan EU-EC-10008574181 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18106 | click or scan EU-EC-10008573902 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Balance disorder (n/a - Recovered/Resolved With Sequelae - Disabling), Dysphagia (n/a - Recovered/Resolved With Sequelae - Disabling), Gait disturbance (n/a - Recovered/Resolved With Sequelae - Disabling), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Loss of consciousness (20min - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Nervous system disorder (n/a - Recovered/Resolved With Sequelae - Disabling), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18107 | click or scan EU-EC-10008573647 | | 2021-05-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 18108 | click or scan EU-EC-10008573633 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bedridden (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 18109 | click or scan EU-EC-10008573064 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (24h - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac failure (24h - Fatal - **Results in Death**), Catarrh (24h - Not Recovered/Not Resolved - Other Medically Important Condition), Condition aggravated (24h - Fatal - **Results in Death**), Cough (24h - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (24h - Not Recovered/Not Resolved - Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (24h - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden cardiac death (24h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 18110 | click or scan EU-EC-10008572554 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18111 | click or scan EU-EC-10008572432 | | 2021-05-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18112 | click or scan EU-EC-10008572431 | | 2021-05-07 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18113 | click or scan EU-EC-10008572429 | | 2021-05-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 18114 | click or scan EU-EC-10008572427 | | 2021-05-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18115 | click or scan EU-EC-10008572419 | | 2021-05-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18116 | click or scan EU-EC-10008572266 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Unknown - ), Dysarthria (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 18117 | click or scan EU-EC-10008572059 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 18118 | click or scan EU-EC-10008572056 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18119 | click or scan EU-EC-10008572046 | | 2021-05-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Kidney infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18120 | click or scan EU-EC-10008572025 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 18121 | click or scan EU-EC-10008571511 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18122 | click or scan EU-EC-10008571409 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18123 | click or scan EU-EC-10008571296 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18124 | click or scan EU-EC-10008571270 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18125 | click or scan EU-EC-10008571238 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18126 | click or scan EU-EC-10008571219 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Hepatic cytolysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [32d - 1 {DF} - n/a]) |
| 18127 | click or scan EU-EC-10008571216 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [27d - 1 {DF} - Intramuscular]) |
| 18128 | click or scan EU-EC-10008571202 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18129 | click or scan EU-EC-10008571129 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 18130 | click or scan EU-EC-10008570957 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 18131 | click or scan EU-EC-10008570834 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18132 | click or scan EU-EC-10008570693 | | 2021-05-07 | Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 18133 | click or scan EU-EC-10008570549 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Terminal state (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18134 | click or scan EU-EC-10008570233 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Male | Oesophageal haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 18135 | click or scan EU-EC-10008569949 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 18136 | click or scan EU-EC-10008569901 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sepsis (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18137 | click or scan EU-EC-10008569899 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypotension (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18138 | click or scan EU-EC-10008569895 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18139 | click or scan EU-EC-10008569893 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Terminal state (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18140 | click or scan EU-EC-10008569756 | | 2021-05-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18141 | click or scan EU-EC-10008569745 | | 2021-05-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Aneurysm (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Vascular anastomosis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18142 | click or scan EU-EC-10008569700 | | 2021-05-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18143 | click or scan EU-EC-10008569370 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18144 | click or scan EU-EC-10008569363 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (1d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18145 | click or scan EU-EC-10008569318 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18146 | click or scan EU-EC-10008569297 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18147** | click or scan EU-EC-10008569291 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18148** | click or scan EU-EC-10008569220 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18149** | click or scan EU-EC-10008569215 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18150** | click or scan EU-EC-10008569192 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18151** | click or scan EU-EC-10008569166 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18152** | click or scan EU-EC-10008569152 | | 2021-05-07 | Non Healthcare Professional | Non EEA | Not Specified | Female | Completed suicide (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Gun shot wound (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18153** | click or scan EU-EC-10008568963 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18154** | click or scan EU-EC-10008568939 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18155** | click or scan EU-EC-10008568893 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18156** | click or scan EU-EC-10008568841 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18157 | click or scan EU-EC-10008568788 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Electrolyte imbalance (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - ), Influenza like illness (n/a - Fatal - **Results in Death**), Renal failure (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18158 | click or scan EU-EC-10008568784 | | 2021-05-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18159 | click or scan EU-EC-10008568780 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18160 | click or scan EU-EC-10008568609 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18161 | click or scan EU-EC-10008568587 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18162 | click or scan EU-EC-10008568554 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18163 | click or scan EU-EC-10008567857 | | 2021-05-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (25d - Fatal - **Results in Death**), Diarrhoea (25d - Fatal - **Results in Death**), Dyspnoea (25d - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Fatal - **Results in Death**), Nausea (25d - Fatal - **Results in Death**), Pyrexia (25d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 18164 | click or scan EU-EC-10008567855 | | 2021-05-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18165 | click or scan EU-EC-10008567847 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Neuropsychiatric symptoms (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18166 | click or scan EU-EC-10008567804 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18167 | click or scan EU-EC-10008567365 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18168 | click or scan EU-EC-10008567351 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Lethargy (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18169 | click or scan EU-EC-10008567297 | | 2021-05-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 18170 | click or scan EU-EC-10008567233 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [64d - n/a - n/a]) |
| 18171 | click or scan EU-EC-10008567146 | | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1s - 1 {DF} - Intramuscular]) |
| 18172 | click or scan EU-EC-10008567061 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18173 | click or scan EU-EC-10008567007 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18174 | click or scan EU-EC-10008566746 | | 2021-05-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Small intestinal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18175 | click or scan EU-EC-10008566743 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18176 | click or scan EU-EC-10008566739 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18177 | click or scan EU-EC-10008566728 | | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Terminal state (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18178 | click or scan EU-EC-10008565997 | | 2021-05-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (2d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Hyperhidrosis (2d - Unknown - Other Medically Important Condition), Nausea (2d - Unknown - Other Medically Important Condition), Pyrexia (2d - Unknown - Other Medically Important Condition), Seizure (2d - Unknown - Other Medically Important Condition), Vomiting (2d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18179 | click or scan EU-EC-10008565981 |  | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Subdural haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18180 | click or scan EU-EC-10008565698 |  | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Infection (1440min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18181 | click or scan EU-EC-10008565628 |  | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18182 | click or scan EU-EC-10008565605 |  | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Apolipoprotein (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18183 | click or scan EU-EC-10008565580 |  | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18184 | click or scan EU-EC-10008565487 |  | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (4d - Fatal - **Results in Death**), COVID-19 (4d - Fatal - **Results in Death**), Urosepsis (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18185 | click or scan EU-EC-10008565371 |  | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiopulmonary failure (1d - Fatal - **Results in Death**), Status epilepticus (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18186 | click or scan EU-EC-10008565330 |  | 2021-05-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 18187 | click or scan EU-EC-10008565300 |  | 2021-05-07 | Healthcare Professional | EEA | 18-64 Years | Female | Breath sounds absent (0d - Fatal - **Results in Death**, Other Medically Important Condition), Mydriasis (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pulse absent (0d - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 18188 | click or scan EU-EC-10008565248 |  | 2021-05-07 | Non Healthcare Professional | EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18189 | click or scan EU-EC-10008564816 | | 2021-05-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18190 | click or scan EU-EC-10008564812 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypotonia (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 18191 | click or scan EU-EC-10008563517 | | 2021-05-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular]) |
| 18192 | click or scan EU-EC-10008561189 | | 2021-05-07 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18193 | click or scan EU-EC-10008562483 | | 2021-05-06 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18194 | click or scan EU-EC-10008562376 | | 2021-05-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Hepatic cirrhosis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18195 | click or scan EU-EC-10008562062 | | 2021-05-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 18196 | click or scan EU-EC-10008561874 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (4d - Fatal - **Results in Death**), Chest pain (3d - Fatal - **Results in Death**), Pain in extremity (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 18197 | click or scan EU-EC-10008561862 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18198 | click or scan EU-EC-10008561860 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Male | Generalised tonic-clonic seizure (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18199 | click or scan EU-EC-10008561857 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 18200 | click or scan EU-EC-10008560917 | | 2021-05-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18201 | click or scan EU-EC-10008560780 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18202 | click or scan EU-EC-10008560647 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Thrombosis (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18203 | click or scan EU-EC-10008560474 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18204 | click or scan EU-EC-10008560120 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18205 | click or scan EU-EC-10008560034 | | 2021-05-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18206 | click or scan EU-EC-10008559956 | | 2021-05-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (37d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Clostridium difficile colitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ear pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Klebsiella infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Lacrimation increased (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - ), Starvation (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18207 | click or scan EU-EC-10008559805 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulseless electrical activity (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18208 | click or scan EU-EC-10008559796 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18209 | click or scan EU-EC-10008559758 | | 2021-05-06 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 18210 | click or scan EU-EC-10008559652 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18211 | click or scan EU-EC-10008559513 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Echocardiogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Emphysema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lumbar vertebral fracture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Procalcitonin normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis prophylaxis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tricuspid valve incompetence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18212 | click or scan EU-EC-10008559442 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18213 | click or scan EU-EC-10008559296 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 18214 | click or scan EU-EC-10008559085 | | 2021-05-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18215 | click or scan EU-EC-10008558976 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18216 | click or scan EU-EC-10008558886 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyslipidaemia (n/a - Fatal - **Results in Death**), Surgery (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18217 | click or scan EU-EC-10008558883 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18218 | click or scan EU-EC-10008558882 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18219 | click or scan EU-EC-10008558756 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18220 | click or scan EU-EC-10008558342 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [3s - 1 {DF} - Intramuscular]) |
| 18221 | click or scan EU-EC-10008558093 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cor pulmonale acute (1d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Deep vein thrombosis (1d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18222 | click or scan EU-EC-10008557496 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 18223 | click or scan EU-EC-10008557044 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Dermatitis bullous (n/a - Fatal - **Results in Death**) | ADENURIC [FEBUXOSTAT] (S - Product used for unknown indication - Unknown - [n/a - n/a - Oral]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), RENVELA [SEVELAMER CARBONATE] (S - Chronic kidney disease - Unknown - [n/a - n/a - Oral]), TRULICITY [DULAGLUTIDE] (S - Type 2 diabetes mellitus - Unknown - [n/a - n/a - Subcutaneous]), [CALCIUM CARBONATE] (S - Product used for unknown indication - Unknown - [n/a - n/a - Oral]) |
| 18224 | click or scan EU-EC-10008557041 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Haemoptysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18225 | click or scan EU-EC-10008557034 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18226 | click or scan EU-EC-10008557006 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 18227 | click or scan EU-EC-10008556979 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |
| 18228 | click or scan EU-EC-10008556966 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| 18229 | click or scan EU-EC-10008556953 | | 2021-05-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18230 | click or scan EU-EC-10008556916 | | 2021-05-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18231 | click or scan EU-EC-10008556895 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18232 | click or scan EU-EC-10008556826 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18233 | click or scan EU-EC-10008556791 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18234 | click or scan EU-EC-10008556783 | | 2021-05-06 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Chest discomfort (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea exertional (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18235 | click or scan EU-EC-10008556782 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18236 | click or scan EU-EC-10008556728 | | 2021-05-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 18237 | click or scan EU-EC-10008556718 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 18238 | click or scan EU-EC-10008556645 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18239 | click or scan EU-EC-10008556154 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (3d - Fatal - **Results in Death**), Diarrhoea (3d - Fatal - **Results in Death**), Haematemesis (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18240 | click or scan EU-EC-10008556130 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18241 | click or scan EU-EC-10008555807 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18242 | click or scan EU-EC-10008555626 | | 2021-05-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haemorrhagic stroke (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Posturing (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18243 | click or scan EU-EC-10008555490 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Arterial thrombosis (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18244 | click or scan EU-EC-10008555326 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18245** | click or scan EU-EC-10008555261 | | 2021-05-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**), Gastrointestinal haemorrhage (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertension (1d - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18246** | click or scan EU-EC-10008555182 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18247** | click or scan EU-EC-10008554533 | | 2021-05-06 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18248** | click or scan EU-EC-10008554496 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18249** | click or scan EU-EC-10008554473 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Leukopenia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphopenia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18250** | click or scan EU-EC-10008554439 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18251** | click or scan EU-EC-10008554434 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18252** | click or scan EU-EC-10008554423 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Male | Acute abdomen (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18253** | click or scan EU-EC-10008554409 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18254** | click or scan EU-EC-10008553752 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **18255** | click or scan EU-EC-10008553155 | | 2021-05-06 | Non Healthcare Professional | EEA | Not Specified | Female | Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18256** | click or scan EU-EC-10008553139 | | 2021-05-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18257** | click or scan EU-EC-10008553100 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | C-reactive protein increased (12d - Fatal - **Results in Death**), Death (12d - Fatal - **Results in Death**), Dyspnoea (12d - Fatal - **Results in Death**), General physical health deterioration (12d - Fatal - **Results in Death**), Oxygen saturation decreased (12d - Fatal - **Results in Death**), Pneumonia (12d - Fatal - **Results in Death**), Pyrexia (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18258** | click or scan EU-EC-10008552491 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Escherichia pyelonephritis (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Klebsiella infection (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **18259** | click or scan EU-EC-10008552472 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Inflammation (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18260** | click or scan EU-EC-10008552397 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18261** | click or scan EU-EC-10008551893 | | 2021-05-06 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18262** | click or scan EU-EC-10008551785 | | 2021-05-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Vaccination site pain (1d - Recovered/Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **18263** | click or scan EU-EC-10008550826 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Male | SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18264** | click or scan EU-EC-10008550320 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **18265** | click or scan EU-EC-10008549980 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **18266** | click or scan EU-EC-10008549970 | | 2021-05-06 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **18267** | click or scan EU-EC-10008547679 | | 2021-05-06 | Healthcare Professional | EEA | More than 85 Years | Female | Coronavirus infection (4d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (4d - Fatal - **Results in Death**), Septic shock (4d - Fatal - **Results in Death**), Vaccination failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18268** | click or scan EU-EC-10008549816 | | 2021-05-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Paralysis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18269** | click or scan EU-EC-10008549642 | | 2021-05-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18270** | click or scan EU-EC-10008549521 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Recovered/Resolved - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Myalgia (n/a - Recovered/Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18271** | click or scan EU-EC-10008549498 | | 2021-05-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blindness (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Full blood count abnormal (n/a - Unknown - ), Memory impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18272** | click or scan EU-EC-10008548957 | | 2021-05-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18273** | click or scan EU-EC-10008548861 | | 2021-05-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18274** | click or scan EU-EC-10008548687 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18275** | click or scan EU-EC-10008548554 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory tract infection (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **18276** | click or scan EU-EC-10008548377 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (31d - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **18277** | click or scan EU-EC-10008547978 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18278** | click or scan EU-EC-10008547956 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1 {DF} - Intramuscular]) |
| **18279** | click or scan EU-EC-10008547621 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Bradycardia (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Circulatory collapse (0d - Fatal - **Results in Death**), Dyspnoea (0d - Not Recovered/Not Resolved - **Results in Death**), Fall (0d - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18280** | click or scan EU-EC-10008547374 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18281** | click or scan EU-EC-10008547226 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18282** | click or scan EU-EC-10008546862 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18283** | click or scan EU-EC-10008546608 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18284** | click or scan EU-EC-10008546570 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18285** | click or scan EU-EC-10008546414 | | 2021-05-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18286** | click or scan EU-EC-10008546199 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18287** | click or scan EU-EC-10008546055 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18288** | click or scan EU-EC-10008545834 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18289** | click or scan EU-EC-10008544589 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Male | Pneumonia (8d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18290** | click or scan EU-EC-10008544510 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **18291** | click or scan EU-EC-10008544233 | | 2021-05-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Gingival pain (n/a - Unknown - Life Threatening), Hypophagia (n/a - Unknown - Life Threatening), Loss of personal independence in daily activities (n/a - Unknown - Life Threatening), Oral infection (n/a - Unknown - Life Threatening), Swelling face (n/a - Unknown - Life Threatening), Toothache (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18292** | click or scan EU-EC-10008544217 | | 2021-05-05 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18293** | click or scan EU-EC-10008544173 | | 2021-05-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18294** | click or scan<br>EU-EC-10008544153 | | 2021-05-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computerised tomogram abdomen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electroencephalogram abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic steatosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperammonaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Magnetic resonance imaging head normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pelvic venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ultrasound Doppler abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ultrasound abdomen normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venogram normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18295** | click or scan<br>EU-EC-10008544091 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Female | Gastrointestinal haemorrhage (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [LITHIUM CARBONATE] (S - Psychotic disorder - n/a - [n/a - 1.2g - Oral]), [OLANZAPINE] (S - Psychotic disorder - n/a - [n/a - 30mg - Oral]), [PERICIAZINE] (S - Psychotic disorder - n/a - [n/a - 200mg - Oral]), [SERTRALINE] (S - Psychotic disorder - n/a - [n/a - 100mg - Oral]), [TRAMADOL HYDROCHLORIDE] (S - Psychotic disorder - n/a - [n/a - 200mg - Oral]) |
| **18296** | click or scan<br>EU-EC-10008544073 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| **18297** | click or scan<br>EU-EC-10008544051 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18298 | click or scan EU-EC-10008544035 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18299 | click or scan EU-EC-10008544024 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18300 | click or scan EU-EC-10008543736 | | 2021-05-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Activated partial thromboplastin time normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anticoagulant therapy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza A virus test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza B virus test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), N-terminal prohormone brain natriuretic peptide increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory syncytial virus test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Status epilepticus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18301 | click or scan EU-EC-10008543707 | | 2021-05-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18302 | click or scan EU-EC-10008543702 | | 2021-05-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18303 | click or scan EU-EC-10008543678 | | 2021-05-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Feeling hot (n/a - Fatal - **Results in Death**), Renal pain (n/a - Fatal - **Results in Death**), Swollen tongue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18304 | click or scan EU-EC-10008543618 | | 2021-05-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (42d - Fatal - **Results in Death**), Dysphagia (42d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18305 | click or scan EU-EC-10008543617 | | 2021-05-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Behaviour disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constipation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypersomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Restlessness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18306 | click or scan EU-EC-10008542558 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 18307 | click or scan EU-EC-10008542503 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Ischaemic stroke (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18308 | click or scan EU-EC-10008542465 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18309 | click or scan EU-EC-10008542421 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18310 | click or scan EU-EC-10008542153 | | 2021-05-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18311 | click or scan EU-EC-10008542075 | | 2021-05-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Computerised tomogram head normal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Gastrointestinal tube insertion (n/a - Fatal - **Results in Death**), Neurological symptom (n/a - Fatal - **Results in Death**), Surgery (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18312 | click or scan EU-EC-10008541726 | | 2021-05-05 | Non Healthcare Professional | EEA | Not Specified | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18313 | click or scan EU-EC-10008541172 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (14d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18314 | click or scan EU-EC-10008541000 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (20d - Fatal - **Results in Death**), COVID-19 pneumonia (10d - Fatal - **Results in Death**), Chills (10d - Fatal - **Results in Death**), Cough (10d - Fatal - **Results in Death**), Decreased appetite (10d - Fatal - **Results in Death**), Diarrhoea (10d - Fatal - **Results in Death**), Fatigue (20d - Fatal - **Results in Death**), Headache (10d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (10d - Fatal - **Results in Death**), Myalgia (20d - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18315 | click or scan EU-EC-10008540993 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Female | Arterial occlusive disease (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18316 | click or scan EU-EC-10008540757 | | 2021-05-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18317 | click or scan EU-EC-10008540756 | | 2021-05-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18318 | click or scan EU-EC-10008540402 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18319 | click or scan EU-EC-10008540400 | | 2021-05-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arterial thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arterial thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest injury (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Embolism (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venous thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Visceral venous thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18320 | click or scan EU-EC-10008540116 | | 2021-05-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Chills (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gait apraxia (n/a - Unknown - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hemianopia (n/a - Unknown - Other Medically Important Condition), Malaise (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18321 | click or scan EU-EC-10008539798 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18322 | click or scan EU-EC-10008539794 | | 2021-05-05 | Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (3d - Fatal - **Results in Death**), Chills (3d - Fatal - **Results in Death**), Dizziness (3d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18323 | click or scan EU-EC-10008539791 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18324** | click or scan EU-EC-10008539456 | | 2021-05-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18325** | click or scan EU-EC-10008539268 | | 2021-05-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Influenza (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18326** | click or scan EU-EC-10008538939 | | 2021-05-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Cerebral haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dysstasia (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18327** | click or scan EU-EC-10008538881 | | 2021-05-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiovascular disorder (n/a - Unknown - ), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Fall (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18328** | click or scan EU-EC-10008538716 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18329** | click or scan EU-EC-10008538697 | | 2021-05-05 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18330** | click or scan EU-EC-10008538657 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Disseminated intravascular coagulation (2d - Fatal - **Results in Death**), Septic shock (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18331** | click or scan EU-EC-10008538048 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **18332** | click or scan EU-EC-10008538042 | | 2021-05-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18333 | click or scan EU-EC-10008537582 | | 2021-05-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18334 | click or scan EU-EC-10008536845 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18335 | click or scan EU-EC-10008536833 | | 2021-05-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), C-reactive protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Hyperhidrosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Hypotension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Leukocytosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Lymphoma (n/a - Fatal - **Results in Death**, Disabling), Neutropenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Pallor (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18336 | click or scan EU-EC-10008536721 | | 2021-05-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Basilar artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thalamic infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18337 | click or scan EU-EC-10008536718 | | 2021-05-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Insomnia (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18338 | click or scan EU-EC-10008536633 | | 2021-05-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cluster headache (3wk - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18339 | click or scan EU-EC-10008535997 | | 2021-05-05 | Non Healthcare Professional | EEA | Not Specified | Male | Aggression (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Irritability (n/a - Fatal - **Results in Death**), Mood swings (n/a - Fatal - **Results in Death**), Personality change (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18340 | click or scan EU-EC-10008535840 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Female | Brain oedema (1d - Fatal - **Results in Death**), Cerebral haemorrhage (1d - Fatal - **Results in Death**), Coma (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18341 | click or scan EU-EC-10008535604 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18342** | click or scan EU-EC-10008535391 | | 2021-05-05 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (11d - Fatal - **Results in Death**), Asthenia (11d - Fatal - **Results in Death**), Dyspnoea exertional (11d - Fatal - **Results in Death**), Ecchymosis (11d - Fatal - **Results in Death**), Oedema peripheral (11d - Fatal - **Results in Death**), Tachycardia (11d - Fatal - **Results in Death**) | BINOCRIT [EPOETIN ALFA] (S - Nephrogenic anaemia - Unknown - [n/a - 20000k[iU] - Subcutaneous]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), PRADAXA 110Â MG HARD CAPSULES [DABIGATRAN ETEXILATE] (S - Atrial fibrillation - Drug withdrawn - [n/a - 220mg - Oral]) |
| **18343** | click or scan EU-EC-10008533371 | | 2021-05-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute myeloid leukaemia (28d - Fatal - **Results in Death**), Asthenia (28d - Fatal - **Results in Death**), Contusion (28d - Fatal - **Results in Death**), Petechiae (28d - Fatal - **Results in Death**), Pyrexia (28d - Fatal - **Results in Death**), Rales (28d - Fatal - **Results in Death**), Thrombocytopenia (28d - Fatal - **Results in Death**), Vomiting (28d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **18344** | click or scan EU-EC-10008534321 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **18345** | click or scan EU-EC-10008534110 | | 2021-05-04 | Healthcare Professional | Non EEA | Not Specified | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18346** | click or scan EU-EC-10008534042 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **18347** | click or scan EU-EC-10008534009 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| **18348** | click or scan EU-EC-10008533707 | | 2021-05-04 | Healthcare Professional | EEA | Not Specified | Not Specified | Anencephaly (n/a - Fatal - **Results in Death**, Congenital Anomaly), Cleft palate (n/a - Not Recovered/Not Resolved - **Results in Death**, Congenital Anomaly), Congenital absence of cranial vault (n/a - Fatal - **Results in Death**, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Recovered/Resolved - **Results in Death**, Congenital Anomaly) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Transplacental]) |
| **18349** | click or scan EU-EC-10008532432 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (18d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Atrial flutter (18d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiomegaly (18d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Dyspnoea (18d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea exertional (18d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleural effusion (18d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary congestion (18d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18350** | click or scan EU-EC-10008532223 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute cardiac event (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18351** | click or scan EU-EC-10008532151 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Lethargy (n/a - Fatal - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18352** | click or scan EU-EC-10008532114 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18353** | click or scan EU-EC-10008532056 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18354** | click or scan EU-EC-10008531740 | | 2021-05-04 | Non Healthcare Professional | EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18355** | click or scan EU-EC-10008531471 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (16d - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18356** | click or scan EU-EC-10008531274 | | 2021-05-04 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18357** | click or scan EU-EC-10008530823 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Petechiae (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **18358** | click or scan EU-EC-10008530236 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18359** | click or scan EU-EC-10008530208 | | 2021-05-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**), Subileus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **18360** | click or scan EU-EC-10008530152 | | 2021-05-04 | Healthcare Professional | EEA | 18-64 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **18361** | click or scan EU-EC-10008530131 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombophlebitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **18362** | click or scan EU-EC-10008530126 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18363 | click or scan EU-EC-10008530099 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Petechiae (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), ELIQUIS [APIXABAN] (S - Atrial fibrillation - Not applicable - [n/a - 5mg - Oral]) |
| 18364 | click or scan EU-EC-10008530076 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 18365 | click or scan EU-EC-10008530060 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 18366 | click or scan EU-EC-10008530037 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18367 | click or scan EU-EC-10008530000 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Hemiplegia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pupils unequal (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18368 | click or scan EU-EC-10008529955 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (14d - Fatal - **Results in Death**), Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 18369 | click or scan EU-EC-10008529954 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 18370 | click or scan EU-EC-10008529950 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 18371 | click or scan EU-EC-10008529948 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Pancreatitis acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 18372 | click or scan EU-EC-10008529931 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Communication disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hemiplegia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18373 | click or scan EU-EC-10008529929 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 18374 | click or scan EU-EC-10008529918 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18375 | click or scan EU-EC-10008529875 | | 2021-05-04 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18376 | click or scan EU-EC-10008529637 | | 2021-05-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - ), Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Illness (n/a - Recovering/Resolving - ), Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18377 | click or scan EU-EC-10008529373 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Not Recovered/Not Resolved - ), Cyanosis (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18378 | click or scan EU-EC-10008529165 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18379 | click or scan EU-EC-10008528933 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18380 | click or scan EU-EC-10008528922 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Anaemia (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Unknown - ), Ileus (n/a - Unknown - Caused/Prolonged Hospitalisation), Subileus (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18381 | click or scan EU-EC-10008528650 | | 2021-05-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18382 | click or scan EU-EC-10008528610 | | 2021-05-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18383** | click or scan EU-EC-10008528436 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Lipase increased (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pancreatitis acute (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), White blood cell count increased (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18384** | click or scan EU-EC-10008528423 | | 2021-05-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18385** | click or scan EU-EC-10008528186 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foaming at mouth (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Metabolic function test (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sputum discoloured (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18386** | click or scan EU-EC-10008527566 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intestinal perforation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **18387** | click or scan EU-EC-10008527180 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18388** | click or scan EU-EC-10008527009 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18389** | click or scan EU-EC-10008526992 | | 2021-05-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Back pain (n/a - Unknown - ), Limb discomfort (n/a - Unknown - ), Organ failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18390** | click or scan EU-EC-10008526948 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18391** | click or scan EU-EC-10008526922 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18392** | click or scan EU-EC-10008526760 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18393** | click or scan EU-EC-10008526745 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18394** | click or scan EU-EC-10008526504 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18395** | click or scan EU-EC-10008526398 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (3d - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18396** | click or scan EU-EC-10008526080 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18397** | click or scan EU-EC-10008526045 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Creatinine renal clearance decreased (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **18398** | click or scan EU-EC-10008526040 | | 2021-05-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Aphonia (n/a - Unknown - Disabling), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Unknown - Disabling), Guillain-Barre syndrome (n/a - Unknown - Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Disabling), Muscular weakness (n/a - Unknown - Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18399** | click or scan EU-EC-10008525909 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| **18400** | click or scan EU-EC-10008525838 | | 2021-05-04 | Non Healthcare Professional | EEA | Not Specified | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Injection site reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18401** | click or scan EU-EC-10008525773 | | 2021-05-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Thrombosis (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18402** | click or scan EU-EC-10008525601 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18403** | click or scan EU-EC-10008525599 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18404** | click or scan EU-EC-10008525476 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Cough (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Nasopharyngitis (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Productive cough (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18405** | click or scan EU-EC-10008525426 | | 2021-05-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18406** | click or scan EU-EC-10008525393 | | 2021-05-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18407** | click or scan EU-EC-10008525351 | | 2021-05-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18408** | click or scan EU-EC-10008525252 | | 2021-05-04 | Healthcare Professional | EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18409** | click or scan EU-EC-10008525100 | | 2021-05-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18410** | click or scan EU-EC-10008524449 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18411** | click or scan EU-EC-10008523974 | | 2021-05-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18412** | click or scan EU-EC-10008523860 | | 2021-05-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Colitis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18413** | click or scan EU-EC-10008523777 | | 2021-05-04 | Healthcare Professional | Non EEA | Not Specified | Female | Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18414** | click or scan EU-EC-10008523693 | | 2021-05-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18415 | click or scan EU-EC-10008523591 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Myelodysplastic syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18416 | click or scan EU-EC-10008523582 | | 2021-05-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Unknown - ), Fall (n/a - Unknown - ), Influenza like illness (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18417 | click or scan EU-EC-10008523124 | | 2021-05-04 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 18418 | click or scan EU-EC-10008522732 | | 2021-05-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18419 | click or scan EU-EC-10008522674 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (3wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18420 | click or scan EU-EC-10008520855 | | 2021-05-04 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 18421 | click or scan EU-EC-10008522621 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypersensitivity (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18422 | click or scan EU-EC-10008522615 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18423 | click or scan EU-EC-10008522606 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18424 | click or scan EU-EC-10008522603 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pneumonia viral (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18425 | click or scan EU-EC-10008522585 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18426 | click or scan EU-EC-10008522573 |  | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18427 | click or scan EU-EC-10008522543 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (2d - Fatal - **Results in Death**), Respiratory arrest (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18428 | click or scan EU-EC-10008522499 |  | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Neurological symptom (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Venous thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18429 | click or scan EU-EC-10008522451 |  | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac death (1d - Fatal - **Results in Death**), Malaise (1d - Unknown - Other Medically Important Condition), Syncope (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18430 | click or scan EU-EC-10008522439 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18431 | click or scan EU-EC-10008522372 |  | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18432 | click or scan EU-EC-10008522367 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18433 | click or scan EU-EC-10008522314 |  | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18434 | click or scan EU-EC-10008522311 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Stress cardiomyopathy (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18435 | click or scan EU-EC-10008522289 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18436 | click or scan EU-EC-10008522269 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18437 | click or scan EU-EC-10008522267 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Feeling abnormal (2d - Not Recovered/Not Resolved - ), Thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18438 | click or scan EU-EC-10008522249 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18439 | click or scan EU-EC-10008522248 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (27d - Fatal - **Results in Death**), Arthritis (27d - Fatal - **Results in Death**), Asthenia (27d - Fatal - **Results in Death**), Cardiac arrest (27d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Disorientation (27d - Fatal - **Results in Death**), Fall (27d - Fatal - **Results in Death**), Joint effusion (27d - Fatal - **Results in Death**), Joint injury (27d - Fatal - **Results in Death**), Nausea (27d - Fatal - **Results in Death**), Pain (27d - Fatal - **Results in Death**), Pneumonia (27d - Fatal - **Results in Death**), Sepsis (27d - Fatal - **Results in Death**), Vomiting (27d - Fatal - **Results in Death**), Walking aid user (27d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18440 | click or scan EU-EC-10008522243 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Hypertension (n/a - Unknown - Other Medically Important Condition), Limb discomfort (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Retching (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18441 | click or scan EU-EC-10008522207 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (1d - Not Recovered/Not Resolved - ), Head injury (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18442 | click or scan EU-EC-10008522140 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18443 | click or scan EU-EC-10008522119 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hyperhidrosis (1d - Not Recovered/Not Resolved - ), Hypotonia (1d - Not Recovered/Not Resolved - ), Musculoskeletal stiffness (1d - Not Recovered/Not Resolved - ), Pain in extremity (1d - Not Recovered/Not Resolved - ), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18444 | click or scan EU-EC-10008522096 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18445 | click or scan EU-EC-10008522086 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18446 | click or scan EU-EC-10008522066 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18447 | click or scan EU-EC-10008522063 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18448 | click or scan EU-EC-10008522037 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18449 | click or scan EU-EC-10008521955 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (12d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Fatigue (12d - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (12d - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (12d - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (12d - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18450 | click or scan EU-EC-10008521866 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [3d - .3mL - Intramuscular]) |
| 18451 | click or scan EU-EC-10008521845 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Female | Acute aortic syndrome (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18452 | click or scan EU-EC-10008521830 | | 2021-05-03 | Healthcare Professional | EEA | Not Specified | Male | Syncope (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [4d - .3mL - Intramuscular]) |
| 18453 | click or scan EU-EC-10008521815 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pain in extremity (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18454 | click or scan EU-EC-10008521541 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (13d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (13d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18455 | click or scan EU-EC-10008521515 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (1d - Fatal - **Results in Death**), Fatigue (1d - Unknown - ), Mobility decreased (1d - Unknown - ), Muscular weakness (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18456 | click or scan EU-EC-10008521514 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18457 | click or scan EU-EC-10008521438 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18458 | click or scan EU-EC-10008521437 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Mouth haemorrhage (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18459 | click or scan EU-EC-10008521423 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dementia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18460 | click or scan EU-EC-10008521379 | | 2021-05-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Disease recurrence (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18461 | click or scan EU-EC-10008521376 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Malaise (n/a - Unknown - ), Transient ischaemic attack (1wk - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18462 | click or scan EU-EC-10008521274 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Defaecation disorder (n/a - Unknown - ), Pulseless electrical activity (1d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18463 | click or scan EU-EC-10008521272 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18464 | click or scan EU-EC-10008521254 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Throat tightness (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18465 | click or scan EU-EC-10008521201 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18466 | click or scan EU-EC-10008521199 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18467 | click or scan EU-EC-10008521197 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (2d - Fatal - **Results in Death**), Cardiac failure (2d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (2d - Unknown - Caused/Prolonged Hospitalisation), Lung infiltration (2d - Unknown - Caused/Prolonged Hospitalisation), Pulseless electrical activity (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18468 | click or scan EU-EC-10008521186 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Colitis ischaemic (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal wall thickening (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematochezia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin decreased (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumatosis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count increased (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18469 | click or scan EU-EC-10008521183 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (8d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18470 | click or scan EU-EC-10008521171 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (1d - Unknown - Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 18471 | click or scan EU-EC-10008520787 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18472 | click or scan EU-EC-10008520766 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (18d - Fatal - **Results in Death**), Pulmonary embolism (18d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18473 | click or scan EU-EC-10008520741 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18474 | click or scan EU-EC-10008520719 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18475 | click or scan EU-EC-10008520715 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (25d - Fatal - **Results in Death**), Condition aggravated (25d - Fatal - **Results in Death**), Death (25d - Fatal - **Results in Death**), Decreased appetite (25d - Fatal - **Results in Death**), Fatigue (25d - Fatal - **Results in Death**), Gastric disorder (25d - Fatal - **Results in Death**), Malaise (25d - Fatal - **Results in Death**), Pain (25d - Fatal - **Results in Death**), Pyrexia (25d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18476** | click or scan EU-EC-10008520690 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18477** | click or scan EU-EC-10008520312 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Clostridium difficile colitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18478** | click or scan EU-EC-10008520307 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza (n/a - Unknown - Caused/Prolonged Hospitalisation), Myasthenia gravis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18479** | click or scan EU-EC-10008520279 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18480** | click or scan EU-EC-10008520276 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18481** | click or scan EU-EC-10008520260 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypertension (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18482** | click or scan EU-EC-10008520178 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dizziness (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hypotension (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pulmonary embolism (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Syncope (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18483** | click or scan EU-EC-10008520119 | | 2021-05-03 | Healthcare Professional | Non EEA | Not Specified | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Product dose omission issue (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18484 | click or scan EU-EC-10008520092 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18485 | click or scan EU-EC-10008520090 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18486 | click or scan EU-EC-10008520081 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Lung cancer metastatic (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18487 | click or scan EU-EC-10008520079 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Spinal compression fracture (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18488 | click or scan EU-EC-10008520047 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18489 | click or scan EU-EC-10008520007 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18490 | click or scan EU-EC-10008519993 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18491 | click or scan EU-EC-10008519965 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18492 | click or scan EU-EC-10008519949 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18493 | click or scan EU-EC-10008519943 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (1d - Fatal - **Results in Death**), Liver disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18494** | click or scan EU-EC-10008519676 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain injury (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (5d - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (5d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18495** | click or scan EU-EC-10008519622 |  | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18496** | click or scan EU-EC-10008519598 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspiration (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Foaming at mouth (n/a - Unknown - Other Medically Important Condition), Food refusal (n/a - Unknown - ), Productive cough (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular - More in ICSR]) |
| **18497** | click or scan EU-EC-10008519567 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Complication associated with device (1d - Fatal - **Results in Death**), Graft haemorrhage (1d - Fatal - **Results in Death**), Malaise (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18498** | click or scan EU-EC-10008519540 |  | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Food refusal (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Pain (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18499** | click or scan EU-EC-10008519361 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Bedridden (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18500** | click or scan EU-EC-10008519162 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Influenza like illness (1d - Unknown - Other Medically Important Condition), Respiratory failure (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18501** | click or scan EU-EC-10008519110 |  | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18502** | click or scan EU-EC-10008519096 |  | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Balance disorder (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Central nervous system lesion (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Embolic stroke (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalitis (8d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lethargy (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Meningitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neck pain (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (13d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vasculitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18503** | click or scan EU-EC-10008518966 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18504** | click or scan EU-EC-10008518535 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Biliary obstruction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cholelithiasis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18505** | click or scan EU-EC-10008518526 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18506** | click or scan EU-EC-10008518492 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18507** | click or scan EU-EC-10008518446 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18508** | click or scan EU-EC-10008518443 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18509** | click or scan EU-EC-10008518438 | | 2021-05-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18510** | click or scan EU-EC-10008518432 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular disorder (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Malaise (1d - Recovered/Resolved - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18511** | click or scan EU-EC-10008518411 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - ), Cardiac disorder (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18512** | click or scan EU-EC-10008518392 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anosmia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Fatal - **Results in Death**), Urinary retention (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18513** | click or scan EU-EC-10008518171 | | 2021-05-03 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18514** | click or scan EU-EC-10008518165 |  | 2021-05-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Brain stem stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18515** | click or scan EU-EC-10008518156 |  | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **18516** | click or scan EU-EC-10008518151 |  | 2021-05-03 | Healthcare Professional | Non EEA | Not Specified | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18517** | click or scan EU-EC-10008518143 |  | 2021-05-03 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **18518** | click or scan EU-EC-10008518048 |  | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]), [CYAMEMAZINE, CYAMEMAZINE TARTRATE] (S - Agitation - Not applicable - [n/a - n/a - Oral]), [TROPATEPINE, TROPATEPINE HYDROCHLORIDE] (S - Parkinsonism - Not applicable - [n/a - 10mg - n/a]) |
| **18519** | click or scan EU-EC-10008518035 |  | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal wall haematoma (n/a - Fatal - **Results in Death**), Hepatic infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **18520** | click or scan EU-EC-10008518019 |  | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - .6mL - Intramuscular]) |
| **18521** | click or scan EU-EC-10008518015 |  | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **18522** | click or scan EU-EC-10008518009 |  | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18523** | click or scan EU-EC-10008517945 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **18524** | click or scan EU-EC-10008517901 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **18525** | click or scan EU-EC-10008517900 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]), [ACARBOSE] (S - n/a - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (S - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - n/a - n/a - [n/a - n/a - n/a]), [FLUINDIONE] (S - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (S - n/a - n/a - [n/a - n/a - n/a]), [GLICLAZIDE] (S - n/a - n/a - [n/a - n/a - n/a]), [MIANSERIN HYDROCHLORIDE] (S - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE] (S - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (S - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (S - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (S - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18526** | click or scan EU-EC-10008517859 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulse absent (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18527** | click or scan EU-EC-10008517843 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18528** | click or scan EU-EC-10008516559 | | 2021-05-03 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Inflammatory marker increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **18529** | click or scan EU-EC-10008516351 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18530 | click or scan EU-EC-10008516350 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18531 | click or scan EU-EC-10008516247 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (3d - Fatal - **Results in Death**), Chills (2d - Fatal - **Results in Death**), Depressed level of consciousness (2d - Fatal - **Results in Death**), Dysphagia (2d - Fatal - **Results in Death**), Muscle spasms (2d - Fatal - **Results in Death**), Pain (2d - Fatal - **Results in Death**), Pruritus (3d - Fatal - **Results in Death**), Restlessness (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), [OXYCODONE HYDROCHLORIDE] (S - Pelvic fracture - n/a - [2d - 5mg - Oral]) |
| 18532 | click or scan EU-EC-10008515909 | | 2021-05-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (5d - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (5d - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18533 | click or scan EU-EC-10008515630 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebellar infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18534 | click or scan EU-EC-10008515574 | | 2021-05-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Unknown - ), Eating disorder (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18535 | click or scan EU-EC-10008515499 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neutropenic sepsis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18536 | click or scan EU-EC-10008515440 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 18537 | click or scan EU-EC-10008515170 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia bacterial (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18538 | click or scan EU-EC-10008515029 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18539 | click or scan EU-EC-10008515017 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18540** | click or scan EU-EC-10008515016 | | 2021-05-03 | Healthcare Professional | EEA | Not Specified | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Retching (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18541** | click or scan EU-EC-10008515013 | | 2021-05-03 | Healthcare Professional | EEA | Not Specified | Female | Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18542** | click or scan EU-EC-10008515012 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18543** | click or scan EU-EC-10008515001 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18544** | click or scan EU-EC-10008514995 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18545** | click or scan EU-EC-10008514862 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (9d - Fatal - **Results in Death**), Incomplete course of vaccination (9d - Fatal - **Results in Death**), Infection (9d - Fatal - **Results in Death**), Respiratory failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **18546** | click or scan EU-EC-10008514860 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (7d - Fatal - **Results in Death**), Drug ineffective (7d - Fatal - **Results in Death**), Oxygen saturation decreased (7d - Fatal - **Results in Death**), Respiratory failure (3d - Fatal - **Results in Death**), Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **18547** | click or scan EU-EC-10008514468 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18548** | click or scan EU-EC-10008514243 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Demyelinating polyneuropathy (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18549** | click or scan EU-EC-10008514198 | | 2021-05-03 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Arrhythmia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18550** | click or scan EU-EC-10008514160 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18551** | click or scan EU-EC-10008514159 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain stem thrombosis (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18552** | click or scan EU-EC-10008514158 | | 2021-05-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18553** | click or scan EU-EC-10008514153 | | 2021-05-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Carotid artery stenosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mental impairment (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18554** | click or scan EU-EC-10008513886 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **18555** | click or scan EU-EC-10008513823 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18556** | click or scan EU-EC-10008513731 | | 2021-05-03 | Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18557** | click or scan EU-EC-10008513286 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **18558** | click or scan EU-EC-10008513141 | | 2021-05-03 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18559** | click or scan EU-EC-10008513025 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18560** | click or scan EU-EC-10008513023 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18561** | click or scan EU-EC-10008512983 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18562** | click or scan EU-EC-10008512939 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Choking (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18563** | click or scan EU-EC-10008512923 | | 2021-05-03 | Healthcare Professional | EEA | 65-85 Years | Male | Atrioventricular block complete (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18564** | click or scan EU-EC-10008512706 | | 2021-05-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18565** | click or scan EU-EC-10008511027 | | 2021-05-02 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18566** | click or scan EU-EC-10008510285 | | 2021-05-02 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (18d - Fatal - **Results in Death**), Cerebral thrombosis (18d - Fatal - **Results in Death**), Nervous system disorder (18d - Fatal - **Results in Death**), Thrombocytopenia (18d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5uL - Intramuscular]) |
| **18567** | click or scan EU-EC-10008510219 | | 2021-05-02 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18568** | click or scan EU-EC-10008503126 | | 2021-05-01 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a]) |
| **18569** | click or scan EU-EC-10008503081 | | 2021-05-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18570 | click or scan EU-EC-10008503025 | | 2021-05-01 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18571 | click or scan EU-EC-10008502871 | | 2021-05-01 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18572 | click or scan EU-EC-10008502849 | | 2021-05-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Coma (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18573 | click or scan EU-EC-10008502085 | | 2021-05-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18574 | click or scan EU-EC-10008502069 | | 2021-05-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18575 | click or scan EU-EC-10008502063 | | 2021-05-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 18576 | click or scan EU-EC-10008502060 | | 2021-05-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18577 | click or scan EU-EC-10008501900 | | 2021-05-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**), Incoherent (n/a - Unknown - ), Malaise (n/a - Unknown - ), Meningitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Pathogen resistance (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18578 | click or scan EU-EC-10008501897 | | 2021-05-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeding disorder (n/a - Unknown - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**), Incoherent (n/a - Unknown - ), Malaise (n/a - Unknown - ), Meningitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18579 | click or scan EU-EC-10008501874 | | 2021-05-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Agonal death struggle (n/a - Fatal - **Results in Death**), Blood pressure increased (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - ), Hypertension (n/a - Fatal - **Results in Death**), Muscle rigidity (n/a - Unknown - ), Nerve stimulation test abnormal (n/a - Unknown - ), Neurological examination (n/a - Unknown - ), Paraesthesia (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Unknown - ), Pupillary reflex impaired (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18580** | click or scan EU-EC-10008501657 | | 2021-05-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Dry throat (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), [ACETYLSALICYLIC ACID] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **18581** | click or scan EU-EC-10008501445 | | 2021-05-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **18582** | click or scan EU-EC-10008500979 | | 2021-05-01 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (0d - Fatal - **Results in Death**), Chest pain (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Fibrin D dimer increased (0d - Fatal - **Results in Death**), Myocardial infarction (0d - Fatal - **Results in Death**), Thrombocytopenia (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **18583** | click or scan EU-EC-10008500889 | | 2021-05-01 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Chronic kidney disease (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Ileostomy (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - n/a]) |
| **18584** | click or scan EU-EC-10008500611 | | 2021-05-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18585** | click or scan EU-EC-10008499914 | | 2021-04-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18586** | click or scan EU-EC-10008499911 | | 2021-04-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18587** | click or scan EU-EC-10008499902 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Embolic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18588** | click or scan EU-EC-10008499893 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18589** | click or scan EU-EC-10008499867 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (17d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18590 | click or scan EU-EC-10008499822 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]) |
| 18591 | click or scan EU-EC-10008499764 | | 2021-04-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18592 | click or scan EU-EC-10008499688 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (2d - Fatal - **Results in Death**), Fatigue (2d - Fatal - **Results in Death**), Hyperhidrosis (2d - Fatal - **Results in Death**), Oxygen saturation decreased (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Tremor (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 18593 | click or scan EU-EC-10008499506 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Feeling abnormal (2d - Unknown - Other Medically Important Condition), Oxygen saturation decreased (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 18594 | click or scan EU-EC-10008499314 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 18595 | click or scan EU-EC-10008499231 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18596 | click or scan EU-EC-10008499135 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic stenosis (1d - Fatal - **Results in Death**), Cardiac failure (1d - Fatal - **Results in Death**), Parkinson's disease (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18597 | click or scan EU-EC-10008499119 | | 2021-04-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18598 | click or scan EU-EC-10008499000 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18599 | click or scan EU-EC-10008498467 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18600** | click or scan EU-EC-10008498037 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18601** | click or scan EU-EC-10008497930 | | 2021-04-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18602** | click or scan EU-EC-10008497730 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18603** | click or scan EU-EC-10008497643 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18604** | click or scan EU-EC-10008496860 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18605** | click or scan EU-EC-10008496840 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Female | Activated partial thromboplastin time prolonged (n/a - Unknown - ), Activated partial thromboplastin time ratio increased (n/a - Unknown - ), Alanine aminotransferase increased (n/a - Unknown - ), Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood alkaline phosphatase increased (n/a - Unknown - ), Blood osmolarity increased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebellar atrophy (n/a - Unknown - Other Medically Important Condition), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Hypothermia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphocyte count decreased (n/a - Unknown - ), Mean cell haemoglobin concentration increased (n/a - Unknown - ), Monocyte count decreased (n/a - Unknown - ), Neutrophil count increased (n/a - Unknown - ), Normochromic normocytic anaemia (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Reticulocyte count increased (n/a - Unknown - ), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **18606** | click or scan EU-EC-10008496785 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pericardial effusion (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18607** | click or scan EU-EC-10008496764 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18608 | click or scan EU-EC-10008495895 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18609 | click or scan EU-EC-10008495852 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 18610 | click or scan EU-EC-10008495248 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Female | Endocarditis bacterial (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18611 | click or scan EU-EC-10008495211 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 18612 | click or scan EU-EC-10008495180 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18613 | click or scan EU-EC-10008495121 | | 2021-04-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18614 | click or scan EU-EC-10008495043 | | 2021-04-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 18615 | click or scan EU-EC-10008495012 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 18616 | click or scan EU-EC-10008495000 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18617 | click or scan EU-EC-10008494999 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18618 | click or scan EU-EC-10008494983 | | 2021-04-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Hypertension (0d - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18619 | click or scan EU-EC-10008494867 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Thrombosis (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18620 | click or scan EU-EC-10008494778 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18621 | click or scan EU-EC-10008494742 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18622 | click or scan EU-EC-10008494689 | | 2021-04-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18623 | click or scan EU-EC-10008494607 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18624 | click or scan EU-EC-10008494534 | | 2021-04-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18625 | click or scan EU-EC-10008494053 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tremor (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18626 | click or scan EU-EC-10008494042 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Unknown]) |
| 18627 | click or scan EU-EC-10008494017 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastric haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18628 | click or scan EU-EC-10008493881 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18629 | click or scan EU-EC-10008493867 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18630 | click or scan EU-EC-10008493803 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18631 | click or scan EU-EC-10008493481 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18632 | click or scan EU-EC-10008493479 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18633 | click or scan EU-EC-10008493475 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypotension (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18634 | click or scan EU-EC-10008493470 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18635 | click or scan EU-EC-10008493422 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - ), Autoimmune haemolytic anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Unknown - ), Cardio-respiratory arrest (24d - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Chromaturia (n/a - Unknown - ), Condition aggravated (n/a - Unknown - ), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Haematochezia (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - ), Impaired work ability (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Normochromic anaemia (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Rash (n/a - Unknown - ), Sinus tachycardia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18636 | click or scan EU-EC-10008493296 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Erythema (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18637** | click or scan EU-EC-10008493186 | | 2021-04-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Coma (n/a - Fatal - **Results in Death**), Diarrhoea (1d - Recovered/Resolved - ), Dysphagia (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Movement disorder (n/a - Not Recovered/Not Resolved - ), Renal impairment (n/a - Fatal - **Results in Death**), Tremor (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **18638** | click or scan EU-EC-10008493181 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18639** | click or scan EU-EC-10008493172 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | C-reactive protein increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Inflammation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18640** | click or scan EU-EC-10008493157 | | 2021-04-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Overdose (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18641** | click or scan EU-EC-10008493135 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Swelling (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18642** | click or scan EU-EC-10008493133 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18643** | click or scan EU-EC-10008493092 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18644** | click or scan EU-EC-10008493022 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18645** | click or scan EU-EC-10008492977 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18646** | click or scan EU-EC-10008492933 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Adverse reaction (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18647** | click or scan EU-EC-10008492924 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18648 | click or scan EU-EC-10008492912 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18649 | click or scan EU-EC-10008492890 |  | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18650 | click or scan EU-EC-10008492885 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Intensive care (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18651 | click or scan EU-EC-10008492842 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Malaise (2d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18652 | click or scan EU-EC-10008492759 |  | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18653 | click or scan EU-EC-10008492730 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18654 | click or scan EU-EC-10008492691 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fall (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hip fracture (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Spinal fracture (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18655 | click or scan EU-EC-10008492676 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18656 | click or scan EU-EC-10008492675 |  | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18657 | click or scan EU-EC-10008492623 |  | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18658 | click or scan EU-EC-10008492552 |  | 2021-04-30 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18659** | click or scan EU-EC-10008492518 |  | 2021-04-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18660** | click or scan EU-EC-10008492507 |  | 2021-04-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18661** | click or scan EU-EC-10008492415 |  | 2021-04-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Unknown - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Unknown - **Results in Death**, Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18662** | click or scan EU-EC-10008492394 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18663** | click or scan EU-EC-10008492391 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18664** | click or scan EU-EC-10008492262 |  | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18665** | click or scan EU-EC-10008492261 |  | 2021-04-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18666** | click or scan EU-EC-10008492202 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Feeling cold (1d - Unknown - ), Illness (1d - Unknown - ), Influenza like illness (1d - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18667** | click or scan EU-EC-10008491995 |  | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Brain injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - ), Pruritus (n/a - Unknown - ), Rash erythematous (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18668** | click or scan EU-EC-10008491825 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Faeces discoloured (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Opisthotonus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Retching (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18669** | click or scan EU-EC-10008491786 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18670** | click or scan EU-EC-10008491755 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18671** | click or scan EU-EC-10008491689 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]) |
| **18672** | click or scan EU-EC-10008491557 | | 2021-04-30 | Healthcare Professional | EEA | 18-64 Years | Male | Nausea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18673** | click or scan EU-EC-10008491499 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Vaccination complication (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18674** | click or scan EU-EC-10008491473 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Nasopharyngitis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Recovered/Resolved With Sequelae - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18675** | click or scan EU-EC-10008491470 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18676** | click or scan EU-EC-10008491299 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Heart rate abnormal (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18677** | click or scan EU-EC-10008491295 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18678** | click or scan EU-EC-10008491248 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18679** | click or scan EU-EC-10008491158 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bacteraemia (n/a - Unknown - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Respiratory disorder (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18680** | click or scan EU-EC-10008490951 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Crepitations (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18681** | click or scan EU-EC-10008490931 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Parkinson's disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urinary retention (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18682** | click or scan EU-EC-10008490900 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18683** | click or scan EU-EC-10008490877 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Generalised oedema (28d - Unknown - Caused/Prolonged Hospitalisation), Hyperammonaemia (28d - Unknown - Caused/Prolonged Hospitalisation), Hypermagnesaemia (28d - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (28d - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (28d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18684** | click or scan EU-EC-10008490696 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18685** | click or scan EU-EC-10008490687 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18686** | click or scan EU-EC-10008490611 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18687** | click or scan EU-EC-10008490605 |  | 2021-04-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18688** | click or scan EU-EC-10008490602 |  | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18689** | click or scan EU-EC-10008490597 |  | 2021-04-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cough (4d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**), SARS-CoV-2 test positive (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18690** | click or scan EU-EC-10008490583 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18691** | click or scan EU-EC-10008490569 |  | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18692** | click or scan EU-EC-10008490562 |  | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18693** | click or scan EU-EC-10008490493 |  | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia aspiration (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18694** | click or scan EU-EC-10008490480 |  | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18695** | click or scan EU-EC-10008490476 |  | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18696** | click or scan EU-EC-10008490474 |  | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18697** | click or scan EU-EC-10008490458 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myeloid leukaemia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18698** | click or scan EU-EC-10008490426 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Cardiac failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18699** | click or scan EU-EC-10008490407 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18700** | click or scan EU-EC-10008490392 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic thrombosis (4d - Fatal - **Results in Death**), Cardiogenic shock (1d - Fatal - **Results in Death**), Coagulopathy (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18701** | click or scan EU-EC-10008490372 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18702** | click or scan EU-EC-10008490280 | | 2021-04-30 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18703** | click or scan EU-EC-10008490211 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18704** | click or scan EU-EC-10008490197 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (9d - Unknown - Other Medically Important Condition), Cardiac disorder (9d - Unknown - Other Medically Important Condition), Cerebral small vessel ischaemic disease (9d - Unknown - Other Medically Important Condition), Chronic obstructive pulmonary disease (9d - Unknown - Other Medically Important Condition), Condition aggravated (9d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Hepatic enzyme abnormal (9d - Unknown - Other Medically Important Condition), Hypertension (9d - Unknown - Other Medically Important Condition), Hypokalaemia (9d - Unknown - Other Medically Important Condition), Hypothyroidism (9d - Unknown - Other Medically Important Condition), Malnutrition (9d - Unknown - Other Medically Important Condition), Mental disorder (9d - Unknown - Other Medically Important Condition), Thrombosis (9d - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18705** | click or scan EU-EC-10008490196 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18706** | click or scan EU-EC-10008490195 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18707** | click or scan EU-EC-10008490126 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Intestinal obstruction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18708** | click or scan EU-EC-10008490020 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac disorder (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary thrombosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18709** | click or scan EU-EC-10008489925 | | 2021-04-30 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac failure acute (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18710** | click or scan EU-EC-10008489662 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18711** | click or scan EU-EC-10008489660 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain abscess (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral mass effect (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Motor dysfunction (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Movement disorder (26d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18712** | click or scan EU-EC-10008489636 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18713** | click or scan EU-EC-10008489563 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hepatic mass (n/a - Unknown - Other Medically Important Condition), Pulmonary mass (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18714** | click or scan EU-EC-10008489536 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dysarthria (n/a - Fatal - **Results in Death**), Fine motor skill dysfunction (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18715** | click or scan EU-EC-10008489523 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18716** | click or scan EU-EC-10008489443 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18717 | click or scan EU-EC-10008489406 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18718 | click or scan EU-EC-10008489392 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18719 | click or scan EU-EC-10008489339 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (6d - Unknown - Other Medically Important Condition), Confusional state (6d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Dysstasia (1d - Unknown - Other Medically Important Condition), Epistaxis (1d - Unknown - Other Medically Important Condition), Fall (6d - Unknown - Other Medically Important Condition), Fatigue (1d - Unknown - Other Medically Important Condition), Lethargy (1d - Unknown - Other Medically Important Condition), Mouth haemorrhage (1d - Unknown - Other Medically Important Condition), Muscular weakness (6d - Unknown - Other Medically Important Condition), Respiratory arrest (1d - Unknown - Other Medically Important Condition), Visual impairment (6d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18720 | click or scan EU-EC-10008489295 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Confusional state (1d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (1d - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (1d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (1d - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (1d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18721 | click or scan EU-EC-10008489208 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18722 | click or scan EU-EC-10008489064 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18723 | click or scan EU-EC-10008489031 | | 2021-04-30 | Healthcare Professional | Non EEA | Not Specified | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18724 | click or scan EU-EC-10008488965 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18725 | click or scan EU-EC-10008488781 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concussion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18726 | click or scan EU-EC-10008488753 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Condition aggravated (n/a - Unknown - ), Diabetes mellitus (3d - Fatal - **Results in Death**), Diabetic complication (3d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Electrolyte imbalance (3d - Fatal - **Results in Death**), Impaired driving ability (n/a - Unknown - ), Myocardial infarction (3d - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18727 | click or scan EU-EC-10008488643 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Asymptomatic COVID-19 (n/a - Not Recovered/Not Resolved - ), Quarantine (12d - Recovered/Resolved - ), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 18728 | click or scan EU-EC-10008488628 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18729 | click or scan EU-EC-10008488621 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (1d - Fatal - **Results in Death**), Dyspepsia (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 18730 | click or scan EU-EC-10008488606 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18731 | click or scan EU-EC-10008488566 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18732 | click or scan EU-EC-10008488562 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18733 | click or scan EU-EC-10008488478 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Necrotising fasciitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18734 | click or scan EU-EC-10008488426 | | 2021-04-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18735 | click or scan EU-EC-10008488424 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiovascular insufficiency (n/a - Fatal - **Results in Death**), Coronary artery occlusion (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18736 | click or scan EU-EC-10008488306 | | 2021-04-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Lethargy (3d - Recovered/Resolved - ), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18737 | click or scan EU-EC-10008488213 | | 2021-04-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cold sweat (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Dehydration (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18738 | click or scan EU-EC-10008488004 | | 2021-04-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18739 | click or scan EU-EC-10008487381 | | 2021-04-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18740 | click or scan EU-EC-10008487259 | | 2021-04-30 | Healthcare Professional | EEA | 18-64 Years | Female | Coma (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18741 | click or scan EU-EC-10008487108 | | 2021-04-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (18d - Fatal - **Results in Death**), Dyspnoea (18d - Fatal - **Results in Death**), Ischaemia (18d - Fatal - **Results in Death**), Lymphadenopathy mediastinal (18d - Fatal - **Results in Death**), Pyrexia (18d - Fatal - **Results in Death**), Retinal artery embolism (18d - Fatal - **Results in Death**), SARS-CoV-2 test negative (18d - Fatal - **Results in Death**), Visual impairment (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18742 | click or scan EU-EC-10008486988 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 18743 | click or scan EU-EC-10008486872 | | 2021-04-30 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 18744 | click or scan EU-EC-10008485978 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18745 | click or scan EU-EC-10008485841 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18746 | click or scan EU-EC-10008485807 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18747 | click or scan EU-EC-10008485660 | | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Male | Mesenteric vein thrombosis (2d - Fatal - **Results in Death**), Portal vein thrombosis (2d - Fatal - **Results in Death**), Splenic vein thrombosis (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18748 | click or scan EU-EC-10008485646 | | 2021-04-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Intracranial aneurysm (2d - Fatal - **Results in Death**), Ruptured cerebral aneurysm (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [8d - 1 {DF} - n/a]) |
| 18749 | click or scan EU-EC-10008485556 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Status epilepticus (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 18750 | click or scan EU-EC-10008485458 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Biliary colic (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18751 | click or scan EU-EC-10008485455 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18752 | click or scan EU-EC-10008485431 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhage intracranial (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 18753 | click or scan EU-EC-10008485397 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (1d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Hepatic failure (1d - Unknown - Other Medically Important Condition), Pulmonary embolism (1d - Unknown - Other Medically Important Condition), Renal failure (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18754 | click or scan EU-EC-10008485376 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18755 | click or scan EU-EC-10008485280 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18756 | click or scan EU-EC-10008485245 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18757 | click or scan EU-EC-10008485109 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18758 | click or scan EU-EC-10008485080 | | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transplant failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18759 | click or scan EU-EC-10008484900 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Unknown - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Rheumatoid arthritis (n/a - Unknown - **Results in Death**), Splenic infarction (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**), Urinary tract infection (n/a - Unknown - **Results in Death**), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 18760 | click or scan EU-EC-10008484612 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18761 | click or scan EU-EC-10008484268 | | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Female | Carotid artery occlusion (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18762 | click or scan EU-EC-10008484267 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18763 | click or scan EU-EC-10008484226 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18764 | click or scan EU-EC-10008484222 | | 2021-04-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Epistaxis (15min - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Arrhythmia - Dose not changed - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Arrhythmia - Dose not changed - [n/a - 40mg - n/a]) |
| 18765 | click or scan EU-EC-10008483897 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**), Oxygen saturation abnormal (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18766 | click or scan EU-EC-10008483863 | | 2021-04-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Blister (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Burn oral cavity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug hypersensitivity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mouth swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Night sweats (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thermal burn (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxic epidermal necrolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Toxicity to various agents (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18767 | click or scan EU-EC-10008483780 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18768 | click or scan EU-EC-10008483767 |  | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18769 | click or scan EU-EC-10008483703 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18770 | click or scan EU-EC-10008483636 |  | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18771 | click or scan EU-EC-10008483338 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18772 | click or scan EU-EC-10008483305 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18773 | click or scan EU-EC-10008483088 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18774 | click or scan EU-EC-10008482998 |  | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18775 | click or scan EU-EC-10008482792 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18776 | click or scan EU-EC-10008482750 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18777 | click or scan EU-EC-10008482613 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1440min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18778** | click or scan EU-EC-10008482580 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18779** | click or scan EU-EC-10008482556 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18780** | click or scan EU-EC-10008482356 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18781** | click or scan EU-EC-10008482028 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (8d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain stem embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral artery embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracardiac thrombus (8d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18782** | click or scan EU-EC-10008482017 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18783** | click or scan EU-EC-10008481666 |  | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **18784** | click or scan EU-EC-10008481613 |  | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **18785** | click or scan EU-EC-10008481573 |  | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular]), SITAGLIPTIN [SITAGLIPTIN] (S - Type 2 diabetes mellitus - n/a - [n/a - 100mg - Oral]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Disease risk factor - n/a - [n/a - 75mg - Oral]), [AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL] (S - Hypertension - n/a - [n/a - 1 {DF} - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Disease risk factor - n/a - [n/a - 10mg - Oral]), [HYDROCHLOROTHIAZIDE] (S - Hypertension - n/a - [n/a - 25mg - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (S - Type 2 diabetes mellitus - n/a - [n/a - 3000mg - Oral]), [SPIRONOLACTONE] (S - n/a - n/a - [n/a - 25mg - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18786 | click or scan EU-EC-10008481486 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure immeasurable (3d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Restlessness (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18787 | click or scan EU-EC-10008481481 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18788 | click or scan EU-EC-10008481459 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18789 | click or scan EU-EC-10008481399 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Malaise (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18790 | click or scan EU-EC-10008481313 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18791 | click or scan EU-EC-10008481288 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemodialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18792 | click or scan EU-EC-10008481155 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Eyelid oedema (n/a - Not Recovered/Not Resolved - ), Fall (n/a - Not Recovered/Not Resolved - ), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Lip oedema (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 18793 | click or scan EU-EC-10008481100 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18794 | click or scan EU-EC-10008481062 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**), Flank pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18795 | click or scan EU-EC-10008481056 | | 2021-04-29 | Healthcare Professional | EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18796 | click or scan EU-EC-10008481039 | | 2021-04-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18797 | click or scan EU-EC-10008480965 | | 2021-04-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18798 | click or scan EU-EC-10008480732 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18799 | click or scan EU-EC-10008480669 | | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (6d - Fatal - **Results in Death**), COVID-19 (2d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Dyspnoea (6d - Fatal - **Results in Death**), Nasopharyngitis (15d - Fatal - **Results in Death**), Pneumonia viral (2d - Fatal - **Results in Death**), Pyrexia (6d - Fatal - **Results in Death**), Respiratory failure (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 18800 | click or scan EU-EC-10008480533 | | 2021-04-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Body temperature increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiovascular insufficiency (n/a - Fatal - **Results in Death**, Life Threatening), Chills (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18801 | click or scan EU-EC-10008480530 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18802 | click or scan EU-EC-10008480365 | | 2021-04-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18803 | click or scan EU-EC-10008480331 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18804 | click or scan EU-EC-10008480202 | | 2021-04-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait inability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Impaired driving ability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18805 | click or scan EU-EC-10008480198 | | 2021-04-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18806 | click or scan EU-EC-10008480097 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18807 | click or scan EU-EC-10008479984 | | 2021-04-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18808 | click or scan EU-EC-10008479980 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aphasia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Asthenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain in extremity (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18809 | click or scan EU-EC-10008479874 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| 18810 | click or scan EU-EC-10008479845 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18811 | click or scan EU-EC-10008479826 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18812 | click or scan EU-EC-10008479807 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18813 | click or scan EU-EC-10008479790 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory acidosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18814** | click or scan EU-EC-10008479778 | | 2021-04-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Unknown - **Results in Death**), Influenza like illness (n/a - Unknown - **Results in Death**), Respiratory rate increased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18815** | click or scan EU-EC-10008479774 | | 2021-04-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18816** | click or scan EU-EC-10008479773 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18817** | click or scan EU-EC-10008479770 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (4d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18818** | click or scan EU-EC-10008479769 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18819** | click or scan EU-EC-10008479763 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18820** | click or scan EU-EC-10008479629 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cyanosis (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18821** | click or scan EU-EC-10008479293 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18822** | click or scan EU-EC-10008479261 | | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18823** | click or scan EU-EC-10008479144 | | 2021-04-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18824** | click or scan EU-EC-10008479132 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ear pain (n/a - Unknown - ), Facial paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeding tube user (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Herpes zoster oticus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - ), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tongue paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18825** | click or scan EU-EC-10008479057 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18826** | click or scan EU-EC-10008479012 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18827** | click or scan EU-EC-10008478994 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18828** | click or scan EU-EC-10008478946 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a]) |
| **18829** | click or scan EU-EC-10008478264 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18830** | click or scan EU-EC-10008478242 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Hospitalisation (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18831** | click or scan EU-EC-10008478207 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18832** | click or scan EU-EC-10008478170 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18833** | click or scan EU-EC-10008478103 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18834** | click or scan EU-EC-10008478082 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Small intestinal obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18835** | click or scan EU-EC-10008477967 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18836** | click or scan EU-EC-10008477664 | | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Female | Venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18837** | click or scan EU-EC-10008477610 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18838** | click or scan EU-EC-10008477608 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18839** | click or scan EU-EC-10008477603 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Decreased appetite (11d - Fatal - **Results in Death**), Diarrhoea (6d - Unknown - ), Fatigue (11d - Fatal - **Results in Death**), Somnolence (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18840** | click or scan EU-EC-10008477599 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18841** | click or scan EU-EC-10008477486 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18842** | click or scan EU-EC-10008477463 | | 2021-04-29 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Brain injury (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Language disorder (n/a - Not Recovered/Not Resolved - ), Post procedural haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18843** | click or scan EU-EC-10008477451 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18844** | click or scan EU-EC-10008477243 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18845** | click or scan EU-EC-10008477236 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18846** | click or scan EU-EC-10008477185 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18847** | click or scan EU-EC-10008477136 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **18848** | click or scan EU-EC-10008477072 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18849** | click or scan EU-EC-10008477017 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18850** | click or scan EU-EC-10008477014 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Aerococcus urinae infection (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hyperthermia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [FOSFOMYCIN] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **18851** | click or scan EU-EC-10008476994 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18852** | click or scan EU-EC-10008476993 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18853** | click or scan EU-EC-10008476953 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Cardiovascular disorder (1d - Fatal - **Results in Death**), Cough (1d - Fatal - **Results in Death**), Cyanosis (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Depressed level of consciousness (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Rales (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18854** | click or scan EU-EC-10008476891 | | 2021-04-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aggression (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Paranoia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18855** | click or scan EU-EC-10008476890 |  | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18856** | click or scan EU-EC-10008476876 |  | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18857** | click or scan EU-EC-10008476874 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (3d - Fatal - **Results in Death**), Cardiac failure (3d - Fatal - **Results in Death**), Hypotension (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **18858** | click or scan EU-EC-10008476873 |  | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18859** | click or scan EU-EC-10008476724 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18860** | click or scan EU-EC-10008476723 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18861** | click or scan EU-EC-10008476713 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Gastrointestinal haemorrhage (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **18862** | click or scan EU-EC-10008476696 |  | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18863** | click or scan EU-EC-10008476663 |  | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18864** | click or scan EU-EC-10008476556 |  | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18865 | click or scan EU-EC-10008476447 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18866 | click or scan EU-EC-10008476405 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18867 | click or scan EU-EC-10008476403 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18868 | click or scan EU-EC-10008476356 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 18869 | click or scan EU-EC-10008476267 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 18870 | click or scan EU-EC-10008476208 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypotension (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 18871 | click or scan EU-EC-10008476073 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Blood calcium decreased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood iron decreased (n/a - Unknown - ), Blood potassium decreased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), Coronary artery stenosis (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Unknown - ), Hypertrophic cardiomyopathy (n/a - Fatal - **Results in Death**), Loss of consciousness (58min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Protein total decreased (n/a - Unknown - ), Prothrombin time prolonged (n/a - Unknown - ), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18872 | click or scan EU-EC-10008476057 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18873 | click or scan EU-EC-10008475971 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18874 | click or scan EU-EC-10008475966 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Dizziness (10d - Unknown - Other Medically Important Condition), Dyspnoea (10d - Unknown - Other Medically Important Condition), Hyperhidrosis (10d - Unknown - Other Medically Important Condition), Myalgia (10d - Unknown - Other Medically Important Condition), Pain (10d - Unknown - Other Medically Important Condition), Palpitations (10d - Unknown - Other Medically Important Condition), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18875** | click or scan EU-EC-10008475877 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18876** | click or scan EU-EC-10008475801 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18877** | click or scan EU-EC-10008475795 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18878** | click or scan EU-EC-10008475771 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18879** | click or scan EU-EC-10008475670 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18880** | click or scan EU-EC-10008475538 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac tamponade (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **18881** | click or scan EU-EC-10008475309 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18882** | click or scan EU-EC-10008475165 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18883** | click or scan EU-EC-10008475154 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18884** | click or scan EU-EC-10008475071 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18885** | click or scan EU-EC-10008475068 | | 2021-04-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Breath sounds abnormal (n/a - Fatal - **Results in Death**), Cerebrovascular accident (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18886** | click or scan EU-EC-10008474977 | | 2021-04-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18887** | click or scan EU-EC-10008474769 | | 2021-04-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **18888** | click or scan EU-EC-10008474183 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| **18889** | click or scan EU-EC-10008474112 | | 2021-04-29 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **18890** | click or scan EU-EC-10008474001 | | 2021-04-29 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **18891** | click or scan EU-EC-10008473380 | | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **18892** | click or scan EU-EC-10008473064 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18893** | click or scan EU-EC-10008472623 | | 2021-04-28 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**), Cerebral venous thrombosis (1d - Fatal - **Results in Death**), Subarachnoid haemorrhage (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **18894** | click or scan EU-EC-10008472619 | | 2021-04-28 | Healthcare Professional | EEA | 18-64 Years | Male | Intracardiac thrombus (2d - Fatal - **Results in Death**), Pulmonary embolism (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18895** | click or scan EU-EC-10008472565 |  | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **18896** | click or scan EU-EC-10008472488 |  | 2021-04-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (1d - Fatal - **Results in Death**), Arrhythmia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **18897** | click or scan EU-EC-10008472466 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18898** | click or scan EU-EC-10008472248 |  | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Hypertension (n/a - Unknown - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paresis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18899** | click or scan EU-EC-10008472168 |  | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18900** | click or scan EU-EC-10008471669 |  | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18901** | click or scan EU-EC-10008471660 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (15d - Fatal - **Results in Death**), General physical health deterioration (15d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18902** | click or scan EU-EC-10008471640 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **18903** | click or scan EU-EC-10008471302 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18904** | click or scan EU-EC-10008470851 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18905 | click or scan EU-EC-10008470778 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18906 | click or scan EU-EC-10008470580 |  | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 18907 | click or scan EU-EC-10008470362 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Feeling hot (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18908 | click or scan EU-EC-10008470346 |  | 2021-04-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18909 | click or scan EU-EC-10008469882 |  | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18910 | click or scan EU-EC-10008469648 |  | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Quadriplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Spinal epidural haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), RIVAROXABAN 15MG TABLET (S - Atrial fibrillation - Drug withdrawn - [n/a - 15mg - n/a]), [NOT AVAILABLE] (S - Acute myocardial infarction - Drug withdrawn - [n/a - 75mg - n/a]) |
| 18911 | click or scan EU-EC-10008469386 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Fatigue (7d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18912 | click or scan EU-EC-10008469324 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (3d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Fatigue (3d - Fatal - **Results in Death**), General physical health deterioration (3d - Fatal - **Results in Death**), Mobility decreased (3d - Fatal - **Results in Death**), Unresponsive to stimuli (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18913 | click or scan EU-EC-10008469313 |  | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18914 | click or scan EU-EC-10008469242 |  | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18915 | click or scan EU-EC-10008469173 |  | 2021-04-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18916 | click or scan EU-EC-10008469121 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |
| 18917 | click or scan EU-EC-10008469081 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 18918 | click or scan EU-EC-10008469029 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18919 | click or scan EU-EC-10008468991 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18920 | click or scan EU-EC-10008468972 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 18921 | click or scan EU-EC-10008468941 |  | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Female | Insomnia (n/a - Not Recovered/Not Resolved - Life Threatening), Suicide attempt (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]), [ZOPICLONE] (S - Insomnia - Drug withdrawn - [10d - n/a - n/a]) |
| 18922 | click or scan EU-EC-10008468908 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 18923 | click or scan EU-EC-10008468889 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 18924 | click or scan EU-EC-10008468525 |  | 2021-04-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18925 | click or scan EU-EC-10008468522 |  | 2021-04-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18926** | click or scan EU-EC-10008468507 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18927** | click or scan EU-EC-10008468497 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Anxiety (n/a - Fatal - **Results in Death**), Feeling hot (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **18928** | click or scan EU-EC-10008467960 | | 2021-04-28 | Healthcare Professional | EEA | 18-64 Years | Female | Coagulopathy (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18929** | click or scan EU-EC-10008467872 | | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18930** | click or scan EU-EC-10008467795 | | 2021-04-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chronic kidney disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mobility decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18931** | click or scan EU-EC-10008467674 | | 2021-04-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (0d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [10s - 1 {DF} - Intramuscular]) |
| **18932** | click or scan EU-EC-10008467428 | | 2021-04-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18933** | click or scan EU-EC-10008467318 | | 2021-04-28 | Healthcare Professional | EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18934** | click or scan EU-EC-10008467302 | | 2021-04-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18935 | click or scan EU-EC-10008467244 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (1d - Unknown - ), Feeling abnormal (n/a - Unknown - ), Headache (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (2d - Unknown - ), Vomiting (2d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18936 | click or scan EU-EC-10008467121 |  | 2021-04-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18937 | click or scan EU-EC-10008466963 |  | 2021-04-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Asymptomatic COVID-19 (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 18938 | click or scan EU-EC-10008466866 |  | 2021-04-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Apathy (n/a - Unknown - ), Cough (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 18939 | click or scan EU-EC-10008466789 |  | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 18940 | click or scan EU-EC-10008466729 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18941 | click or scan EU-EC-10008466640 |  | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Bedridden (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Motor dysfunction (n/a - Fatal - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 18942 | click or scan EU-EC-10008466530 |  | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18943 | click or scan EU-EC-10008465931 |  | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18944 | click or scan EU-EC-10008465901 |  | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18945 | click or scan EU-EC-10008465797 | | 2021-04-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18946 | click or scan EU-EC-10008465554 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18947 | click or scan EU-EC-10008464653 | | 2021-04-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Epistaxis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Haemoptysis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Increased viscosity of upper respiratory secretion (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Secretion discharge (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18948 | click or scan EU-EC-10008464652 | | 2021-04-28 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18949 | click or scan EU-EC-10008464363 | | 2021-04-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18950 | click or scan EU-EC-10008464347 | | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 18951 | click or scan EU-EC-10008464288 | | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dementia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18952 | click or scan EU-EC-10008464223 | | 2021-04-28 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18953 | click or scan EU-EC-10008463962 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Female | Mesenteric vascular occlusion (n/a - Fatal - **Results in Death**, Life Threatening), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 18954 | click or scan EU-EC-10008463679 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (2h - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **18955** | click or scan EU-EC-10008463647 | | 2021-04-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Foaming at mouth (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18956** | click or scan EU-EC-10008463610 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **18957** | click or scan EU-EC-10008463350 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18958** | click or scan EU-EC-10008463214 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18959** | click or scan EU-EC-10008463092 | | 2021-04-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18960** | click or scan EU-EC-10008462840 | | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **18961** | click or scan EU-EC-10008462835 | | 2021-04-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **18962** | click or scan EU-EC-10008462833 | | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18963** | click or scan EU-EC-10008462665 | | 2021-04-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Bedridden (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Immune system disorder (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18964** | click or scan EU-EC-10008462656 | | 2021-04-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18965** | click or scan EU-EC-10008462591 | | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18966** | click or scan EU-EC-10008462422 | | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18967** | click or scan EU-EC-10008462342 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18968** | click or scan EU-EC-10008462239 | | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18969** | click or scan EU-EC-10008462210 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Aphasia (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Carotid artery occlusion (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Leukocytosis (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **18970** | click or scan EU-EC-10008462143 | | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18971** | click or scan EU-EC-10008462018 | | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18972** | click or scan EU-EC-10008462005 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **18973** | click or scan EU-EC-10008462004 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **18974** | click or scan EU-EC-10008461909 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Mobility decreased (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 18975 | click or scan EU-EC-10008461820 | | 2021-04-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2d - n/a - n/a]) |
| 18976 | click or scan EU-EC-10008461799 | | 2021-04-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 18977 | click or scan EU-EC-10008461776 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 18978 | click or scan EU-EC-10008461650 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18979 | click or scan EU-EC-10008461492 | | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18980 | click or scan EU-EC-10008461327 | | 2021-04-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 18981 | click or scan EU-EC-10008460458 | | 2021-04-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18982 | click or scan EU-EC-10008459988 | | 2021-04-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory rate decreased (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 18983 | click or scan EU-EC-10008459639 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (5d - Fatal - **Results in Death**), Diarrhoea (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 18984 | click or scan EU-EC-10008459156 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral artery occlusion (14d - Fatal - **Results in Death**), Hemiparesis (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **18985** | click or scan EU-EC-10008459152 | | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **18986** | click or scan EU-EC-10008459143 | | 2021-04-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Decreased appetite (22d - Fatal - **Results in Death**), Nausea (22d - Fatal - **Results in Death**), Pyrexia (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **18987** | click or scan EU-EC-10008459033 | | 2021-04-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| **18988** | click or scan EU-EC-10008458946 | | 2021-04-28 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Tremor (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **18989** | click or scan EU-EC-10008458687 | | 2021-04-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **18990** | click or scan EU-EC-10008458519 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Basophil count increased (n/a - Unknown - ), Blood creatinine increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Blood magnesium decreased (n/a - Unknown - ), Blood phosphorus decreased (n/a - Unknown - ), Blood urea increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eosinophil count decreased (n/a - Unknown - ), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Immature granulocyte count increased (n/a - Unknown - ), Lymphocyte count decreased (n/a - Unknown - ), Monocyte count increased (n/a - Unknown - ), Neutrophil count increased (n/a - Unknown - ), Nucleated red cells (n/a - Unknown - ), Platelet count increased (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Red cell distribution width increased (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **18991** | click or scan EU-EC-10008458474 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **18992** | click or scan EU-EC-10008458115 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Disabling), Disorientation (n/a - Fatal - **Results in Death**, Disabling), Dyspnoea (n/a - Fatal - **Results in Death**, Disabling), Gait disturbance (n/a - Fatal - **Results in Death**, Disabling), Hallucination, visual (n/a - Fatal - **Results in Death**, Disabling), Psychomotor hyperactivity (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **18993** | click or scan EU-EC-10008458051 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 18994 | click or scan EU-EC-10008458046 | | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]), [ACENOCOUMAROL] (S - Atrial fibrillation - Not applicable - [n/a - n/a - Oral]) |
| 18995 | click or scan EU-EC-10008457042 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 18996 | click or scan EU-EC-10008456673 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 18997 | click or scan EU-EC-10008456528 | | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Male | Arterial thrombosis (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 18998 | click or scan EU-EC-10008456174 | | 2021-04-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 18999 | click or scan EU-EC-10008455948 | | 2021-04-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19000 | click or scan EU-EC-10008455661 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | Apathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cachexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 19001 | click or scan EU-EC-10008454350 | | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 19002 | click or scan EU-EC-10008454334 | | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic transformation stroke (2d - Fatal - **Results in Death**), Hypertension (2d - Fatal - **Results in Death**), Ischaemic stroke (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), OLANZAPINE [OLANZAPINE] (S - Bipolar disorder - Dose not changed - [n/a - n/a - Oral]) |
| 19003 | click or scan EU-EC-10008454323 | | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Myocardial infarction - Drug withdrawn - [4246d - 160mg - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19004** | click or scan EU-EC-10008454320 |  | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular]) |
| **19005** | click or scan EU-EC-10008454317 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1 {DF} - Intramuscular]) |
| **19006** | click or scan EU-EC-10008454313 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19007** | click or scan EU-EC-10008454301 |  | 2021-04-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 30ug - Intramuscular]) |
| **19008** | click or scan EU-EC-10008454294 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Female | Brain stem haematoma (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 12mL - Intramuscular]) |
| **19009** | click or scan EU-EC-10008454245 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19010** | click or scan EU-EC-10008454244 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Disseminated intravascular coagulation (7d - Fatal - **Results in Death**), Thrombocytopenia (7d - Fatal - **Results in Death**), Thrombosis (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19011** | click or scan EU-EC-10008454237 |  | 2021-04-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **19012** | click or scan EU-EC-10008454227 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous thrombosis (34d - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **19013** | click or scan EU-EC-10008454226 |  | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19014** | click or scan EU-EC-10008454201 |  | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **19015** | click or scan EU-EC-10008454187 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **19016** | click or scan EU-EC-10008454186 |  | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **19017** | click or scan EU-EC-10008454168 |  | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19018** | click or scan EU-EC-10008454161 |  | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19019** | click or scan EU-EC-10008453531 |  | 2021-04-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19020** | click or scan EU-EC-10008453012 |  | 2021-04-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anal incontinence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test negative (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Supine position (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary incontinence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Subcutaneous]) |
| **19021** | click or scan EU-EC-10008452926 |  | 2021-04-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (0d - Fatal - **Results in Death**), Skin haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19022** | click or scan EU-EC-10008452800 |  | 2021-04-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19023 | click or scan EU-EC-10008452448 | | 2021-04-27 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19024 | click or scan EU-EC-10008452362 | | 2021-04-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (6d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19025 | click or scan EU-EC-10008452191 | | 2021-04-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Night sweats (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Urinary incontinence (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 19026 | click or scan EU-EC-10008452145 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Psychomotor retardation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19027 | click or scan EU-EC-10008451403 | | 2021-04-27 | Healthcare Professional | EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19028 | click or scan EU-EC-10008451383 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19029 | click or scan EU-EC-10008451202 | | 2021-04-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 19030 | click or scan EU-EC-10008450672 | | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19031 | click or scan EU-EC-10008450480 | | 2021-04-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), B-cell lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Influenza (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19032 | click or scan EU-EC-10008450277 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19033 | click or scan EU-EC-10008450039 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 19034 | click or scan EU-EC-10008450023 | | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Female | Epilepsy (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19035 | click or scan EU-EC-10008449774 | | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Male | Accident at work (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 19036 | click or scan EU-EC-10008449675 | | 2021-04-27 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19037 | click or scan EU-EC-10008449089 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | Pseudomonas infection (n/a - Fatal - **Results in Death**), Urine output decreased (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 19038 | click or scan EU-EC-10008448854 | | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 19039 | click or scan EU-EC-10008448561 | | 2021-04-27 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Fatal - **Results in Death**), Chills (n/a - Recovered/Resolved - ), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19040 | click or scan EU-EC-10008448287 | | 2021-04-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) |
| 19041 | click or scan EU-EC-10008447766 | | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19042 | click or scan EU-EC-10008447288 | | 2021-04-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Influenza like illness (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ), Injection site reaction (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19043** | click or scan EU-EC-10008447128 | | 2021-04-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19044** | click or scan EU-EC-10008446615 | | 2021-04-27 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19045** | click or scan EU-EC-10008445981 | | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **19046** | click or scan EU-EC-10008443714 | | 2021-04-27 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **19047** | click or scan EU-EC-10008444704 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **19048** | click or scan EU-EC-10008444348 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Epistaxis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19049** | click or scan EU-EC-10008444171 | | 2021-04-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Autonomic nervous system imbalance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Motor dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Personality change (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **19050** | click or scan EU-EC-10008443943 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19051** | click or scan EU-EC-10008443652 | | 2021-04-26 | Healthcare Professional | EEA | 18-64 Years | Female | Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19052** | click or scan EU-EC-10008442959 | | 2021-04-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Agitation (n/a - Unknown - Caused/Prolonged Hospitalisation), Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**), Lactic acidosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhythm idioventricular (n/a - Unknown - Caused/Prolonged Hospitalisation), Septic shock (1d - Fatal - **Results in Death**), Subcutaneous abscess (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19053 | click or scan EU-EC-10008442884 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19054 | click or scan EU-EC-10008442716 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19055 | click or scan EU-EC-10008442666 | | 2021-04-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19056 | click or scan EU-EC-10008442164 | | 2021-04-26 | Healthcare Professional | Non EEA | Not Specified | Male | Acute coronary syndrome (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19057 | click or scan EU-EC-10008442050 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Unknown - ), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19058 | click or scan EU-EC-10008441930 | | 2021-04-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19059 | click or scan EU-EC-10008441557 | | 2021-04-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19060 | click or scan EU-EC-10008441525 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19061 | click or scan EU-EC-10008441472 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19062 | click or scan EU-EC-10008440966 | | 2021-04-26 | Healthcare Professional | EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19063** | click or scan EU-EC-10008440397 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **19064** | click or scan EU-EC-10008440332 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Pallor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19065** | click or scan EU-EC-10008440319 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (0d - Fatal - **Results in Death**), Sopor (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19066** | click or scan EU-EC-10008440149 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1 {DF} - Intramuscular]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (S - Arrhythmia - Drug withdrawn - [n/a - 200mg - Oral]) |
| **19067** | click or scan EU-EC-10008440139 | | 2021-04-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19068** | click or scan EU-EC-10008440131 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Vertigo (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19069** | click or scan EU-EC-10008440088 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **19070** | click or scan EU-EC-10008440068 | | 2021-04-26 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **19071** | click or scan EU-EC-10008440067 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Miosis (n/a - Fatal - **Results in Death**), Rectal haemorrhage (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19072** | click or scan EU-EC-10008440066 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19073** | click or scan EU-EC-10008440062 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19074** | click or scan EU-EC-10008440051 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **19075** | click or scan EU-EC-10008440045 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cough (4d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular]) |
| **19076** | click or scan EU-EC-10008439836 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aggression (n/a - Fatal - **Results in Death**), Mood altered (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **19077** | click or scan EU-EC-10008439830 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **19078** | click or scan EU-EC-10008439743 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19079** | click or scan EU-EC-10008439705 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **19080** | click or scan EU-EC-10008439317 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **19081** | click or scan EU-EC-10008438791 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19082** | click or scan EU-EC-10008438787 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19083** | click or scan EU-EC-10008438760 | | 2021-04-26 | Non Healthcare Professional | EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19084** | click or scan EU-EC-10008438755 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19085** | click or scan EU-EC-10008438751 |  | 2021-04-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19086** | click or scan EU-EC-10008438247 |  | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**), Subdural haematoma (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Underdose (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19087** | click or scan EU-EC-10008438087 |  | 2021-04-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **19088** | click or scan EU-EC-10008437827 |  | 2021-04-26 | Non Healthcare Professional | EEA | More than 85 Years | Male | Decreased appetite (3d - Fatal - **Results in Death**), Dysgeusia (4d - Fatal - **Results in Death**), Dysphagia (4d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), Hypotension (0d - Fatal - **Results in Death**), Myocardial infarction (0d - Fatal - **Results in Death**), Vomiting (3d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19089** | click or scan EU-EC-10008437716 |  | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19090** | click or scan EU-EC-10008437645 |  | 2021-04-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **19091** | click or scan EU-EC-10008437625 |  | 2021-04-26 | Non Healthcare Professional | EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19092** | click or scan EU-EC-10008437496 |  | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), [IBUPROFEN] (S - n/a - Not applicable - [n/a - 400mg - Oral]) |
| **19093** | click or scan EU-EC-10008436519 |  | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **19094** | click or scan EU-EC-10008436120 |  | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac ventricular thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19095** | click or scan EU-EC-10008436052 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19096** | click or scan EU-EC-10008436028 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19097** | click or scan EU-EC-10008435932 | | 2021-04-26 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Arrhythmia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19098** | click or scan EU-EC-10008435926 | | 2021-04-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19099** | click or scan EU-EC-10008435922 | | 2021-04-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Productive cough (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19100** | click or scan EU-EC-10008435919 | | 2021-04-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19101** | click or scan EU-EC-10008435770 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **19102** | click or scan EU-EC-10008434917 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19103** | click or scan EU-EC-10008434916 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19104** | click or scan EU-EC-10008434914 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19105 | click or scan EU-EC-10008434908 | | 2021-04-26 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Bone cancer metastatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19106 | click or scan EU-EC-10008434883 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19107 | click or scan EU-EC-10008434682 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Blood pressure fluctuation (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Skin warm (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 19108 | click or scan EU-EC-10008434347 | | 2021-04-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (7d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19109 | click or scan EU-EC-10008434175 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19110 | click or scan EU-EC-10008433987 | | 2021-04-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19111 | click or scan EU-EC-10008433980 | | 2021-04-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19112 | click or scan EU-EC-10008433970 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19113 | click or scan EU-EC-10008433712 | | 2021-04-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19114 | click or scan EU-EC-10008433709 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19115** | click or scan EU-EC-10008433705 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19116** | click or scan EU-EC-10008433696 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19117** | click or scan EU-EC-10008433694 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19118** | click or scan EU-EC-10008433370 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular arrhythmia (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19119** | click or scan EU-EC-10008433237 | | 2021-04-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**), Renal failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19120** | click or scan EU-EC-10008433177 | | 2021-04-26 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Immobile (n/a - Fatal - **Results in Death**), Irritability (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rhinitis (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - n/a]) |
| **19121** | click or scan EU-EC-10008432364 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Malaise (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **19122** | click or scan EU-EC-10008432080 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **19123** | click or scan EU-EC-10008431888 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Portal vein thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19124** | click or scan EU-EC-10008431887 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19125** | click or scan<br>EU-EC-10008431873 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal discomfort (n/a - Unknown - ), COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haemolysis (n/a - Unknown - Other Medically Important Condition), Haemorrhage (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain (5d - Recovered/Resolved - ), Sepsis (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19126** | click or scan<br>EU-EC-10008431382 | | 2021-04-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute respiratory distress syndrome (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aggression (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arteriosclerosis (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atelectasis (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrial fibrillation (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomegaly (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cholecystectomy (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diastolic dysfunction (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyslipidaemia (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endocarditis staphylococcal (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatomegaly (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypernatraemia (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inferior vena cava dilatation (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Iron deficiency anaemia (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mitral valve incompetence (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Obesity (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Polyuria (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcal infection (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (15645min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19127** | click or scan<br>EU-EC-10008431337 | | 2021-04-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Completed suicide (n/a - Fatal - **Results in Death**), Tinnitus (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19128** | click or scan<br>EU-EC-10008431334 | | 2021-04-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19129** | click or scan<br>EU-EC-10008431159 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Male | Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19130 | click or scan EU-EC-10008431109 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19131 | click or scan EU-EC-10008431068 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Male | Decreased appetite (15d - Fatal - **Results in Death**), Dyspnoea (15d - Fatal - **Results in Death**), Fall (15d - Fatal - **Results in Death**), Hypotension (15d - Fatal - **Results in Death**), Jaundice (15d - Fatal - **Results in Death**), Metabolic acidosis (15d - Fatal - **Results in Death**), Psychomotor retardation (15d - Fatal - **Results in Death**), Renal impairment (15d - Fatal - **Results in Death**), Respiratory failure (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19132 | click or scan EU-EC-10008431056 | | 2021-04-26 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 19133 | click or scan EU-EC-10008431003 | | 2021-04-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19134 | click or scan EU-EC-10008430672 | | 2021-04-25 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19135 | click or scan EU-EC-10008430006 | | 2021-04-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haematoma (n/a - Unknown - **Results in Death**), Cerebral haemorrhage (5d - Fatal - **Results in Death**), Confusional state (n/a - Unknown - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Peripheral swelling (n/a - Unknown - **Results in Death**), Pneumonia aspiration (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19136 | click or scan EU-EC-10008429434 | | 2021-04-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 19137 | click or scan EU-EC-10008429344 | | 2021-04-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19138 | click or scan EU-EC-10008429145 | | 2021-04-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Herpes zoster (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19139 | click or scan EU-EC-10008429134 | | 2021-04-25 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19140 | click or scan EU-EC-10008429129 | | 2021-04-25 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19141 | click or scan EU-EC-10008429044 | | 2021-04-25 | Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19142 | click or scan EU-EC-10008429043 | | 2021-04-25 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19143 | click or scan EU-EC-10008429042 | | 2021-04-25 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19144 | click or scan EU-EC-10008428867 | | 2021-04-25 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19145 | click or scan EU-EC-10008428056 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19146 | click or scan EU-EC-10008428055 | | 2021-04-24 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19147 | click or scan EU-EC-10008427855 | | 2021-04-24 | Healthcare Professional | EEA | 18-64 Years | Female | Acidosis (n/a - Fatal - **Results in Death**), Anaphylactic reaction (2h - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Bradypnoea (n/a - Fatal - **Results in Death**), Bronchospasm (n/a - Fatal - **Results in Death**), Hyperlactacidaemia (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19148 | click or scan EU-EC-10008427571 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19149 | click or scan EU-EC-10008427491 | | 2021-04-24 | Healthcare Professional | Non EEA | Not Specified | Female | Embolism (n/a - Unknown - **Results in Death**), Head discomfort (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19150 | click or scan EU-EC-10008427482 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Unknown - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19151 | click or scan EU-EC-10008427315 |  | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Acute coronary syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Acute myocardial infarction (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coronary artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Portal vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Visceral venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 19152 | click or scan EU-EC-10008427288 |  | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Partial seizures (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19153 | click or scan EU-EC-10008427285 |  | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (14d - Fatal - **Results in Death**, Life Threatening), Dizziness (n/a - Unknown - **Results in Death**, Life Threatening), Haematoma (n/a - Unknown - **Results in Death**, Life Threatening), Jugular vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening), Somnolence (n/a - Unknown - **Results in Death**, Life Threatening), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19154 | click or scan EU-EC-10008427270 |  | 2021-04-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Feeling abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Infarction (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Mental impairment (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pulmonary embolism (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Sepsis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vomiting projectile (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19155 | click or scan EU-EC-10008426609 |  | 2021-04-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19156 | click or scan EU-EC-10008426393 |  | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**), Mesenteric haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19157 | click or scan EU-EC-10008426392 |  | 2021-04-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19158 | click or scan EU-EC-10008426000 | | 2021-04-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Not Recovered/Not Resolved - **Results in Death**), Gait inability (n/a - Not Recovered/Not Resolved - **Results in Death**), Left ventricular dysfunction (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19159 | click or scan EU-EC-10008425959 | | 2021-04-24 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19160 | click or scan EU-EC-10008425844 | | 2021-04-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**), Vasculitis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19161 | click or scan EU-EC-10008425127 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Embolism (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19162 | click or scan EU-EC-10008424450 | | 2021-04-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19163 | click or scan EU-EC-10008424188 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**), Peripheral swelling (n/a - Unknown - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Syncope (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19164 | click or scan EU-EC-10008424160 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 19165 | click or scan EU-EC-10008423530 | | 2021-04-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19166 | click or scan EU-EC-10008422870 | | 2021-04-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19167 | click or scan EU-EC-10008422542 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19168 | click or scan EU-EC-10008422533 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**), Cough (n/a - Unknown - **Results in Death**), Crepitations (n/a - Unknown - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Feeling of body temperature change (n/a - Unknown - **Results in Death**), Lethargy (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pulmonary embolism (3d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Thirst decreased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19169** | click or scan EU-EC-10008422527 | | 2021-04-24 | Healthcare Professional | Non EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **19170** | click or scan EU-EC-10008422521 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19171** | click or scan EU-EC-10008422520 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain oedema (n/a - Unknown - **Results in Death**), Bundle branch block left (n/a - Unknown - **Results in Death**), Cardiac arrest (n/a - Unknown - **Results in Death**), Cardiogenic shock (n/a - Unknown - **Results in Death**), Fibrin D dimer increased (n/a - Unknown - **Results in Death**), Left ventricular dysfunction (n/a - Unknown - **Results in Death**), Myocarditis (2d - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Troponin T increased (n/a - Unknown - **Results in Death**), Ventricular fibrillation (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19172** | click or scan EU-EC-10008422149 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic cirrhosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19173** | click or scan EU-EC-10008422110 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial ischaemia (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Ill-defined disorder - Unknown - [1d - n/a - Intramuscular]) |
| **19174** | click or scan EU-EC-10008421216 | | 2021-04-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Condition aggravated (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Hypoacusis (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **19175** | click or scan EU-EC-10008420977 | | 2021-04-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **19176** | click or scan EU-EC-10008420434 | | 2021-04-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **19177** | click or scan EU-EC-10008420154 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haematoma (n/a - Unknown - **Results in Death**), Embolism (n/a - Unknown - **Results in Death**), Haemorrhage (n/a - Unknown - **Results in Death**), Muscle spasms (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **19178** | click or scan EU-EC-10008418867 | | 2021-04-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Viral infection (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19179 | click or scan EU-EC-10008417379 | | 2021-04-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19180 | click or scan EU-EC-10008417316 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiac dysfunction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Hepatic failure (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Viral infection (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19181 | click or scan EU-EC-10008417304 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 19182 | click or scan EU-EC-10008417270 | | 2021-04-24 | Healthcare Professional | EEA | More than 85 Years | Female | Dysarthria (1d - Fatal - **Results in Death**), Dysphagia (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]) |
| 19183 | click or scan EU-EC-10008417263 | | 2021-04-24 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (21d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]) |
| 19184 | click or scan EU-EC-10008417191 | | 2021-04-24 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 19185 | click or scan EU-EC-10008417063 | | 2021-04-24 | Healthcare Professional | EEA | More than 85 Years | Female | Anaphylactic shock (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 19186 | click or scan EU-EC-10008416914 | | 2021-04-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Road traffic accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19187 | click or scan EU-EC-10008416876 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 19188 | click or scan EU-EC-10008416656 | | 2021-04-23 | Healthcare Professional | EEA | 18-64 Years | Male | Lividity (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vaccination site reaction (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19189 | click or scan EU-EC-10008416500 | | 2021-04-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19190 | click or scan EU-EC-10008416407 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19191 | click or scan EU-EC-10008416126 | | 2021-04-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19192 | click or scan EU-EC-10008415608 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg/m2 - Intramuscular]) |
| 19193 | click or scan EU-EC-10008415526 | | 2021-04-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial pressure increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19194 | click or scan EU-EC-10008415009 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19195 | click or scan EU-EC-10008414979 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 19196 | click or scan EU-EC-10008414972 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19197 | click or scan EU-EC-10008414898 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19198 | click or scan EU-EC-10008414893 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19199** | click or scan EU-EC-10008414883 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **19200** | click or scan EU-EC-10008414878 | | 2021-04-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| **19201** | click or scan EU-EC-10008414868 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19202** | click or scan EU-EC-10008414835 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19203** | click or scan EU-EC-10008414690 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Pallor (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| **19204** | click or scan EU-EC-10008414660 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **19205** | click or scan EU-EC-10008414578 | | 2021-04-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Illness (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19206** | click or scan EU-EC-10008414558 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19207** | click or scan EU-EC-10008413601 | | 2021-04-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **19208** | click or scan EU-EC-10008413162 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19209** | click or scan EU-EC-10008413147 |  | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **19210** | click or scan EU-EC-10008412934 |  | 2021-04-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19211** | click or scan EU-EC-10008412849 |  | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **19212** | click or scan EU-EC-10008412839 |  | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19213** | click or scan EU-EC-10008412824 |  | 2021-04-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19214** | click or scan EU-EC-10008412777 |  | 2021-04-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **19215** | click or scan EU-EC-10008412574 |  | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **19216** | click or scan EU-EC-10008412533 |  | 2021-04-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Blood glucose decreased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19217** | click or scan EU-EC-10008412526 |  | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemoglobin abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19218 | click or scan EU-EC-10008412440 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (4d - Fatal - **Results in Death**), Pulmonary embolism (4d - Fatal - **Results in Death**), Respiratory distress (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19219 | click or scan EU-EC-10008412393 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 19220 | click or scan EU-EC-10008412340 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 19221 | click or scan EU-EC-10008412270 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19222 | click or scan EU-EC-10008411903 | | 2021-04-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal disorder (n/a - Unknown - ), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19223 | click or scan EU-EC-10008411870 | | 2021-04-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 19224 | click or scan EU-EC-10008411659 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling of body temperature change (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Musculoskeletal stiffness (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Staring (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 19225 | click or scan EU-EC-10008411617 | | 2021-04-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19226 | click or scan EU-EC-10008411587 | | 2021-04-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Feeling hot (n/a - Unknown - ), Nervousness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19227 | click or scan EU-EC-10008411585 | | 2021-04-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19228 | click or scan EU-EC-10008411497 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19229 | click or scan EU-EC-10008411392 | | 2021-04-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19230 | click or scan EU-EC-10008411388 | | 2021-04-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 19231 | click or scan EU-EC-10008411355 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Gangrene (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal ischaemia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19232 | click or scan EU-EC-10008411353 | | 2021-04-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dementia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 19233 | click or scan EU-EC-10008411297 | | 2021-04-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 19234 | click or scan EU-EC-10008411230 | | 2021-04-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19235 | click or scan EU-EC-10008411229 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19236 | click or scan EU-EC-10008411211 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 19237 | click or scan EU-EC-10008411035 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dialysis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19238** | click or scan EU-EC-10008410859 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Retinal vascular thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19239** | click or scan EU-EC-10008410847 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19240** | click or scan EU-EC-10008410294 | | 2021-04-23 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **19241** | click or scan EU-EC-10008410209 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19242** | click or scan EU-EC-10008410189 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19243** | click or scan EU-EC-10008410185 | | 2021-04-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19244** | click or scan EU-EC-10008410023 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Influenza B virus test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary mass (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19245** | click or scan EU-EC-10008409901 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Male | Influenza like illness (20d - Fatal - **Results in Death**), Pyrexia (20d - Fatal - **Results in Death**), Sepsis (20d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19246** | click or scan EU-EC-10008409716 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| **19247** | click or scan EU-EC-10008409405 | | 2021-04-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiomegaly (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hepatomegaly (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19248** | click or scan EU-EC-10008409100 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19249** | click or scan EU-EC-10008409038 | | 2021-04-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **19250** | click or scan EU-EC-10008408958 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **19251** | click or scan EU-EC-10008407873 | | 2021-04-23 | Non Healthcare Professional | EEA | 18-64 Years | Female | Discomfort (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Oxygen consumption (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19252** | click or scan EU-EC-10008407842 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19253** | click or scan EU-EC-10008407381 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19254** | click or scan EU-EC-10008407068 | | 2021-04-23 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **19255** | click or scan EU-EC-10008406512 | | 2021-04-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19256** | click or scan EU-EC-10008406259 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19257 | click or scan EU-EC-10008406023 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19258 | click or scan EU-EC-10008405880 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19259 | click or scan EU-EC-10008405855 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [LEUPRORELIN ACETATE] (S - Prostate cancer - Not applicable - [1107d - n/a - n/a]) |
| 19260 | click or scan EU-EC-10008405795 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown - More in ICSR]), INVEGA 3 MG PROLONGED-RELEASE TABLET [PALIPERIDONE] (S - n/a - Drug withdrawn - [n/a - 3mg - Oral]) |
| 19261 | click or scan EU-EC-10008405754 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19262 | click or scan EU-EC-10008405731 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19263 | click or scan EU-EC-10008405718 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (2d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**), Renal failure (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19264 | click or scan EU-EC-10008405623 | | 2021-04-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Unknown - ), Insomnia (2d - Unknown - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - ), Respiration abnormal (1d - Unknown - Caused/Prolonged Hospitalisation), Restlessness (3d - Unknown - ), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (1d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19265 | click or scan EU-EC-10008405546 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Pain in extremity (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19266 | click or scan EU-EC-10008405345 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19267 | click or scan EU-EC-10008405082 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19268 | click or scan EU-EC-10008405069 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19269 | click or scan EU-EC-10008404914 | | 2021-04-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19270 | click or scan EU-EC-10008404868 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (1d - Fatal - **Results in Death**), Nasal congestion (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 19271 | click or scan EU-EC-10008404793 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Ecchymosis (n/a - Fatal - **Results in Death**), Lividity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 19272 | click or scan EU-EC-10008404046 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthma (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 19273 | click or scan EU-EC-10008403809 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19274 | click or scan EU-EC-10008403766 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 19275 | click or scan EU-EC-10008403593 | | 2021-04-22 | Non Healthcare Professional | EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19276** | click or scan EU-EC-10008403577 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19277** | click or scan EU-EC-10008403399 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19278** | click or scan EU-EC-10008403336 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19279** | click or scan EU-EC-10008403328 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **19280** | click or scan EU-EC-10008403281 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Gallbladder mass (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19281** | click or scan EU-EC-10008403280 | | 2021-04-22 | Healthcare Professional | EEA | Not Specified | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cluster headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19282** | click or scan EU-EC-10008403251 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19283** | click or scan EU-EC-10008403046 | | 2021-04-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Unknown - **Results in Death**), Death (1d - Fatal - **Results in Death**), Hernia (n/a - Recovered/Resolved - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **19284** | click or scan EU-EC-10008402646 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**), Thrombocytopenic purpura (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **19285** | click or scan EU-EC-10008402448 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cough (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19286 | click or scan EU-EC-10008402407 | | 2021-04-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Coronary artery occlusion (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19287 | click or scan EU-EC-10008402343 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gallbladder mass (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19288 | click or scan EU-EC-10008402256 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19289 | click or scan EU-EC-10008402011 | | 2021-04-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19290 | click or scan EU-EC-10008401655 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19291 | click or scan EU-EC-10008401616 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19292 | click or scan EU-EC-10008401573 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19293 | click or scan EU-EC-10008401447 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Hallucination (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 19294 | click or scan EU-EC-10008401386 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19295** | click or scan EU-EC-10008401385 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19296** | click or scan EU-EC-10008401370 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19297** | click or scan EU-EC-10008401076 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **19298** | click or scan EU-EC-10008400992 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Confusional state (2d - Recovered/Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ) | CANNABIDIOL [CANNABIDIOL] (S - n/a - n/a - [n/a - n/a - Oral]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - 1 {DF} - Intramuscular]), [METOCLOPRAMIDE, METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (S - Product used for unknown indication - n/a - [1d - 5mg - n/a]), [MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE] (S - Pain - n/a - [1d - 1 {DF} - n/a]), [MORPHINE SULFATE] (S - Pain - n/a - [n/a - 2 {DF} - n/a]) |
| **19299** | click or scan EU-EC-10008400985 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **19300** | click or scan EU-EC-10008400913 | | 2021-04-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19301** | click or scan EU-EC-10008400878 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **19302** | click or scan EU-EC-10008400864 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19303** | click or scan EU-EC-10008400848 | | 2021-04-22 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19304** | click or scan EU-EC-10008400817 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19305** | click or scan EU-EC-10008400773 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19306** | click or scan EU-EC-10008400766 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Testicular failure (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19307** | click or scan EU-EC-10008400753 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19308** | click or scan EU-EC-10008400743 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **19309** | click or scan EU-EC-10008400633 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19310** | click or scan EU-EC-10008399809 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19311** | click or scan EU-EC-10008399777 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19312** | click or scan EU-EC-10008399775 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Hypersensitivity (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19313** | click or scan EU-EC-10008399752 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Pneumonia aspiration (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**), Vaccination complication (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19314 | click or scan EU-EC-10008399575 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19315 | click or scan EU-EC-10008399550 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Pulse absent (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19316 | click or scan EU-EC-10008399447 | | 2021-04-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cognitive disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19317 | click or scan EU-EC-10008399374 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Male | Acute pulmonary oedema (1d - Fatal - **Results in Death**), Cardiac failure (1d - Fatal - **Results in Death**), Cardiovascular disorder (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), Lactic acidosis (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**), Troponin T increased (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19318 | click or scan EU-EC-10008399373 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Respiratory disorder (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19319 | click or scan EU-EC-10008399371 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19320 | click or scan EU-EC-10008399337 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Haemorrhagic diathesis (n/a - Fatal - **Results in Death**), Respiratory tract haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| 19321 | click or scan EU-EC-10008399334 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Dyspnoea (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19322 | click or scan EU-EC-10008399321 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rhinitis (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19323 | click or scan EU-EC-10008399180 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19324 | click or scan EU-EC-10008398877 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypotension (4d - Fatal - **Results in Death**), Pneumonia (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19325** | click or scan EU-EC-10008398488 |  | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Apathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **19326** | click or scan EU-EC-10008398390 |  | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Fatal - **Results in Death**), Ulcer (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular - More in ICSR]) |
| **19327** | click or scan EU-EC-10008398361 |  | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pain (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19328** | click or scan EU-EC-10008398287 |  | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19329** | click or scan EU-EC-10008398123 |  | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19330** | click or scan EU-EC-10008398114 |  | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19331** | click or scan EU-EC-10008398067 |  | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19332** | click or scan EU-EC-10008398065 |  | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19333** | click or scan EU-EC-10008398059 |  | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19334** | click or scan EU-EC-10008398047 |  | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19335** | click or scan EU-EC-10008397956 |  | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Coronary artery occlusion (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19336** | click or scan EU-EC-10008397707 |  | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Escherichia infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19337** | click or scan EU-EC-10008397690 |  | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19338** | click or scan EU-EC-10008397364 |  | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **19339** | click or scan EU-EC-10008397360 |  | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Body temperature increased (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Pain (n/a - Unknown - ), Urinary tract infection (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19340** | click or scan EU-EC-10008397239 |  | 2021-04-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary oedema (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19341** | click or scan EU-EC-10008397235 |  | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradyphrenia (n/a - Unknown - ), Cerebral disorder (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dysphagia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Irregular sleep wake rhythm disorder (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **19342** | click or scan EU-EC-10008396959 |  | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Memory impairment (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19343** | click or scan EU-EC-10008396885 |  | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **19344** | click or scan EU-EC-10008396669 |  | 2021-04-22 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyskinesia (4d - Unknown - ), Dyspnoea (0d - Unknown - ), Fatigue (1d - Unknown - ), Tremor (4d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19345** | click or scan EU-EC-10008396650 | | 2021-04-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19346** | click or scan EU-EC-10008396640 | | 2021-04-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Influenza like illness (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Ventricular fibrillation (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19347** | click or scan EU-EC-10008396621 | | 2021-04-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19348** | click or scan EU-EC-10008396610 | | 2021-04-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19349** | click or scan EU-EC-10008396604 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Renal failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19350** | click or scan EU-EC-10008396582 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19351** | click or scan EU-EC-10008396418 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Staphylococcal infection (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19352** | click or scan EU-EC-10008396397 | | 2021-04-22 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19353** | click or scan EU-EC-10008396304 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19354** | click or scan EU-EC-10008396245 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain upper (17d - Fatal - **Results in Death**), Vomiting (17d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19355** | click or scan EU-EC-10008396204 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19356** | click or scan EU-EC-10008396043 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (2d - Unknown - Caused/Prolonged Hospitalisation), Death (2d - Fatal - **Results in Death**), Hypotension (2d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19357** | click or scan EU-EC-10008396005 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19358** | click or scan EU-EC-10008395952 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cellulitis (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Rash (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19359** | click or scan EU-EC-10008395922 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Basal ganglia haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19360** | click or scan EU-EC-10008395788 | | 2021-04-22 | Non Healthcare Professional | EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19361** | click or scan EU-EC-10008395743 | | 2021-04-22 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening), Embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19362** | click or scan EU-EC-10008395731 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (2d - Not Recovered/Not Resolved - ), Feeling abnormal (2d - Not Recovered/Not Resolved - ), Influenza like illness (2d - Not Recovered/Not Resolved - ), Myalgia (2d - Not Recovered/Not Resolved - ), Mydriasis (2d - Not Recovered/Not Resolved - ), Myocardial infarction (2d - Fatal - **Results in Death**), Nausea (2d - Not Recovered/Not Resolved - ), Pain (2d - Not Recovered/Not Resolved - ), Pallor (2d - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| **19363** | click or scan EU-EC-10008395581 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19364** | click or scan EU-EC-10008395560 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Dyspnoea (1d - Unknown - ), Respiratory arrest (1d - Unknown - Other Medically Important Condition), Respiratory tract congestion (n/a - Unknown - ), Rhinitis (n/a - Unknown - ), Suspected COVID-19 (n/a - Unknown - ), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19365** | click or scan EU-EC-10008395467 | | 2021-04-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Unknown - ), Haematemesis (n/a - Unknown - ), Internal haemorrhage (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19366 | click or scan EU-EC-10008395404 | | 2021-04-22 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19367 | click or scan EU-EC-10008395397 | | 2021-04-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19368 | click or scan EU-EC-10008395203 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19369 | click or scan EU-EC-10008394379 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 19370 | click or scan EU-EC-10008394304 | | 2021-04-22 | Healthcare Professional | EEA | 65-85 Years | Male | Hypotensive crisis (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19371 | click or scan EU-EC-10008394075 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Sopor (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19372 | click or scan EU-EC-10008394062 | | 2021-04-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19373 | click or scan EU-EC-10008394024 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 19374 | click or scan EU-EC-10008393941 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Sopor (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 19375 | click or scan EU-EC-10008393738 | | 2021-04-22 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19376 | click or scan EU-EC-10008393655 | | 2021-04-22 | Healthcare Professional | EEA | Not Specified | Female | Infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19377 | click or scan EU-EC-10008393645 | | 2021-04-22 | Healthcare Professional | EEA | Not Specified | Male | Infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19378 | click or scan EU-EC-10008393611 | | 2021-04-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cognitive disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Flushing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Polyuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 19379 | click or scan EU-EC-10008393599 | | 2021-04-22 | Healthcare Professional | EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19380 | click or scan EU-EC-10008393452 | | 2021-04-21 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral venous sinus thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 19381 | click or scan EU-EC-10008393077 | | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - Other Medically Important Condition), Bedridden (n/a - Unknown - Disabling), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Life Threatening), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - ), Somnolence (n/a - Unknown - Life Threatening), Thirst (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 19382 | click or scan EU-EC-10008392600 | | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 19383 | click or scan EU-EC-10008392461 | | 2021-04-21 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 19384 | click or scan EU-EC-10008392130 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19385** | click or scan EU-EC-10008392104 | | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Metastatic neoplasm (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19386** | click or scan EU-EC-10008391881 | | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19387** | click or scan EU-EC-10008391873 | | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19388** | click or scan EU-EC-10008391494 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Recovering/Resolving - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **19389** | click or scan EU-EC-10008391078 | | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Duodenal ulcer perforation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Peritonitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19390** | click or scan EU-EC-10008390956 | | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **19391** | click or scan EU-EC-10008390856 | | 2021-04-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **19392** | click or scan EU-EC-10008390810 | | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19393** | click or scan EU-EC-10008390704 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19394** | click or scan EU-EC-10008390657 | | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19395** | click or scan EU-EC-10008390630 |  | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19396** | click or scan EU-EC-10008390608 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Food refusal (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19397** | click or scan EU-EC-10008390563 |  | 2021-04-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Pyrexia (3d - Recovered/Resolved - ), Skin discolouration (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19398** | click or scan EU-EC-10008390537 |  | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19399** | click or scan EU-EC-10008390526 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19400** | click or scan EU-EC-10008390348 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19401** | click or scan EU-EC-10008390241 |  | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19402** | click or scan EU-EC-10008389952 |  | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **19403** | click or scan EU-EC-10008389786 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19404** | click or scan EU-EC-10008389434 |  | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19405** | click or scan EU-EC-10008389247 |  | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19406** | click or scan EU-EC-10008389246 |  | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19407** | click or scan EU-EC-10008389245 |  | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea exertional (3d - Fatal - **Results in Death**), General physical health deterioration (3d - Fatal - **Results in Death**), Sudden death (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19408** | click or scan EU-EC-10008389244 |  | 2021-04-21 | Non Healthcare Professional | EEA | More than 85 Years | Female | Haemoptysis (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19409** | click or scan EU-EC-10008389149 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **19410** | click or scan EU-EC-10008389148 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19411** | click or scan EU-EC-10008389109 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19412** | click or scan EU-EC-10008388687 |  | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **19413** | click or scan EU-EC-10008388621 |  | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19414** | click or scan EU-EC-10008388615 |  | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Male | Phlebitis (2d - Not Recovered/Not Resolved - Life Threatening), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19415 | click or scan EU-EC-10008388588 |  | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 19416 | click or scan EU-EC-10008388496 |  | 2021-04-21 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 19417 | click or scan EU-EC-10008388409 |  | 2021-04-21 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19418 | click or scan EU-EC-10008388407 |  | 2021-04-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19419 | click or scan EU-EC-10008388403 |  | 2021-04-21 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19420 | click or scan EU-EC-10008388203 |  | 2021-04-21 | Healthcare Professional | EEA | More than 85 Years | Female | Asymptomatic COVID-19 (n/a - Not Recovered/Not Resolved - ), Marasmus (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| 19421 | click or scan EU-EC-10008388181 |  | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 19422 | click or scan EU-EC-10008388073 |  | 2021-04-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 19423 | click or scan EU-EC-10008387950 |  | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 19424 | click or scan EU-EC-10008387883 |  | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19425 | click or scan EU-EC-10008387807 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19426 | click or scan EU-EC-10008387502 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Epilepsy (n/a - Unknown - Other Medically Important Condition), Obstructive airways disorder (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19427 | click or scan EU-EC-10008387325 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19428 | click or scan EU-EC-10008387321 | | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Allergy to vaccine (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Angioedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypothermia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash maculo-papular (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract oedema (n/a - Unknown - Other Medically Important Condition), Skin exfoliation (n/a - Unknown - Caused/Prolonged Hospitalisation), Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Swelling face (n/a - Unknown - Caused/Prolonged Hospitalisation), Toxic epidermal necrolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19429 | click or scan EU-EC-10008387320 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19430 | click or scan EU-EC-10008387317 | | 2021-04-21 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19431 | click or scan EU-EC-10008387222 | | 2021-04-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19432 | click or scan EU-EC-10008387212 | | 2021-04-21 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersomnia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypokinesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Odynophagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19433** | click or scan EU-EC-10008387135 | | 2021-04-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **19434** | click or scan EU-EC-10008386969 | | 2021-04-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19435** | click or scan EU-EC-10008386929 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **19436** | click or scan EU-EC-10008386895 | | 2021-04-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19437** | click or scan EU-EC-10008386653 | | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19438** | click or scan EU-EC-10008386476 | | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Seizure (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19439** | click or scan EU-EC-10008386197 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19440** | click or scan EU-EC-10008386028 | | 2021-04-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **19441** | click or scan EU-EC-10008385739 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19442** | click or scan EU-EC-10008385625 | | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Acute respiratory failure (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19443 | click or scan EU-EC-10008385406 | | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19444 | click or scan EU-EC-10008384670 | | 2021-04-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19445 | click or scan EU-EC-10008384664 | | 2021-04-21 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19446 | click or scan EU-EC-10008384659 | | 2021-04-21 | Non Healthcare Professional | EEA | Not Specified | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19447 | click or scan EU-EC-10008384468 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Life Threatening), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 19448 | click or scan EU-EC-10008384406 | | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19449 | click or scan EU-EC-10008384403 | | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Transient ischaemic attack - Not applicable - [n/a - n/a - n/a]) |
| 19450 | click or scan EU-EC-10008384232 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19451 | click or scan EU-EC-10008384229 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 19452 | click or scan EU-EC-10008384131 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19453** | click or scan EU-EC-10008383973 | | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19454** | click or scan EU-EC-10008383869 | | 2021-04-21 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (4d - Recovered/Resolved - ), Injection site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19455** | click or scan EU-EC-10008383507 | | 2021-04-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypotension (12d - Fatal - **Results in Death**), Respiratory arrest (12d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19456** | click or scan EU-EC-10008383044 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **19457** | click or scan EU-EC-10008382910 | | 2021-04-21 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **19458** | click or scan EU-EC-10008382841 | | 2021-04-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19459** | click or scan EU-EC-10008382676 | | 2021-04-21 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19460** | click or scan EU-EC-10008382613 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **19461** | click or scan EU-EC-10008381303 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19462** | click or scan EU-EC-10008380922 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Cerebral infarction (2d - Fatal - **Results in Death**), Cerebral thrombosis (2d - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **19463** | click or scan EU-EC-10008380805 | | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (3d - Fatal - **Results in Death**), Disorientation (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19464** | click or scan EU-EC-10008380646 | | 2021-04-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19465** | click or scan EU-EC-10008380622 | | 2021-04-21 | Healthcare Professional | EEA | More than 85 Years | Male | Oxygen saturation decreased (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **19466** | click or scan EU-EC-10008378834 | | 2021-04-21 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19467** | click or scan EU-EC-10008378824 | | 2021-04-21 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19468** | click or scan EU-EC-10008380539 | | 2021-04-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Intracranial aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **19469** | click or scan EU-EC-10008380238 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic aneurysm (n/a - Unknown - Other Medically Important Condition), Bacterial sepsis (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - ), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - ), Gastrointestinal infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Malaise (n/a - Recovered/Resolved - ), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vasculitis (n/a - Unknown - Other Medically Important Condition), Viral sepsis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR]) |
| **19470** | click or scan EU-EC-10008380088 | | 2021-04-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **19471** | click or scan EU-EC-10008379992 | | 2021-04-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac valve disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Haemoptysis (n/a - Unknown - Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19472** | click or scan EU-EC-10008379989 | | 2021-04-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19473** | click or scan EU-EC-10008379975 | | 2021-04-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (1d - Fatal - **Results in Death**), Cough (1d - Unknown - Other Medically Important Condition), Dyspnoea (1d - Unknown - Other Medically Important Condition), Headache (1d - Unknown - Other Medically Important Condition), Myalgia (1d - Unknown - Other Medically Important Condition), Pyrexia (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19474** | click or scan EU-EC-10008379852 | | 2021-04-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Aphonia (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Bronchitis (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19475** | click or scan EU-EC-10008379792 | | 2021-04-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19476** | click or scan EU-EC-10008379640 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Female | Acute coronary syndrome (4d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19477** | click or scan EU-EC-10008379588 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular - More in ICSR]) |
| **19478** | click or scan EU-EC-10008379531 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Unknown]) |
| **19479** | click or scan EU-EC-10008379496 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **19480** | click or scan EU-EC-10008378270 | | 2021-04-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **19481** | click or scan EU-EC-10008378185 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19482** | click or scan EU-EC-10008377538 | | 2021-04-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (3d - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19483** | click or scan EU-EC-10008377428 | | 2021-04-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Organ failure (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19484** | click or scan EU-EC-10008377381 | | 2021-04-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **19485** | click or scan EU-EC-10008377361 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Bronchitis (6d - Fatal - **Results in Death**), Cardiac failure (8d - Fatal - **Results in Death**), Haematoma (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **19486** | click or scan EU-EC-10008376871 | | 2021-04-20 | Healthcare Professional | EEA | Not Specified | Male | Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19487** | click or scan EU-EC-10008376862 | | 2021-04-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19488** | click or scan EU-EC-10008376673 | | 2021-04-20 | Non Healthcare Professional | EEA | Not Specified | Male | Aphasia (n/a - Not Recovered/Not Resolved - **Results in Death**), Dysphagia (n/a - Not Recovered/Not Resolved - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Gait inability (n/a - Unknown - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypoxia (16d - Fatal - **Results in Death**), Illness (n/a - Unknown - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**), Paralysis (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**), Tremor (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19489** | click or scan EU-EC-10008376327 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19490** | click or scan EU-EC-10008375818 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **19491** | click or scan EU-EC-10008375809 | | 2021-04-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (3d - Unknown - ), Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Influenza like illness (3d - Unknown - ), Vaccination site pain (4d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19492 | click or scan EU-EC-10008375572 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Epilepsy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19493 | click or scan EU-EC-10008374611 | | 2021-04-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Accidental overdose (1d - Fatal - **Results in Death**), Chills (3d - Not Recovered/Not Resolved - ), Dyspnoea (3d - Not Recovered/Not Resolved - ), Malaise (3d - Not Recovered/Not Resolved - ), Myalgia (3d - Not Recovered/Not Resolved - ), Pyrexia (3d - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19494 | click or scan EU-EC-10008374523 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (S - Pulmonary embolism - Not applicable - [n/a - 2 {DF} - Oral]) |
| 19495 | click or scan EU-EC-10008374508 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [25d - 1 {DF} - Intramuscular]) |
| 19496 | click or scan EU-EC-10008374477 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19497 | click or scan EU-EC-10008374462 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Male | Influenza like illness (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 19498 | click or scan EU-EC-10008374451 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 19499 | click or scan EU-EC-10008374446 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 19500 | click or scan EU-EC-10008374381 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 19501 | click or scan EU-EC-10008374341 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19502 | click or scan EU-EC-10008374076 | | 2021-04-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19503 | click or scan EU-EC-10008374055 | | 2021-04-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood potassium increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19504 | click or scan EU-EC-10008374012 | | 2021-04-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 19505 | click or scan EU-EC-10008373632 | | 2021-04-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Communication disorder (n/a - Unknown - ), Crying (n/a - Unknown - ), Decreased appetite (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19506 | click or scan EU-EC-10008373335 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Male | Haemorrhagic stroke (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 19507 | click or scan EU-EC-10008373302 | | 2021-04-20 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19508 | click or scan EU-EC-10008372893 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**), Renal infarct (n/a - Fatal - **Results in Death**), Spleen disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19509 | click or scan EU-EC-10008372570 | | 2021-04-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 19510 | click or scan EU-EC-10008372547 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 19511 | click or scan EU-EC-10008371995 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19512 | click or scan EU-EC-10008371741 | | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Malaise (2d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19513 | click or scan EU-EC-10008371552 |  | 2021-04-20 | Healthcare Professional | EEA | Not Specified | Female | Plasma cell myeloma (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19514 | click or scan EU-EC-10008370646 |  | 2021-04-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19515 | click or scan EU-EC-10008370327 |  | 2021-04-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19516 | click or scan EU-EC-10008370321 |  | 2021-04-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Organ failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19517 | click or scan EU-EC-10008369959 |  | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disease progression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19518 | click or scan EU-EC-10008369876 |  | 2021-04-20 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (2d - Fatal - **Results in Death**), Resuscitation (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19519 | click or scan EU-EC-10008369846 |  | 2021-04-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Tenosynovitis stenosans (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19520 | click or scan EU-EC-10008369726 |  | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19521 | click or scan EU-EC-10008369712 |  | 2021-04-20 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening), Heparin-induced thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19522 | click or scan EU-EC-10008369705 |  | 2021-04-20 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Paranasal sinus inflammation (n/a - Fatal - **Results in Death**), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19523 | click or scan EU-EC-10008369703 | | 2021-04-20 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19524 | click or scan EU-EC-10008369663 | | 2021-04-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dysphagia (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19525 | click or scan EU-EC-10008368982 | | 2021-04-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19526 | click or scan EU-EC-10008368932 | | 2021-04-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19527 | click or scan EU-EC-10008368903 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19528 | click or scan EU-EC-10008367969 | | 2021-04-20 | Non Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19529 | click or scan EU-EC-10008367140 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (10d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 19530 | click or scan EU-EC-10008366867 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 19531 | click or scan EU-EC-10008366840 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 19532 | click or scan EU-EC-10008366644 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19533 | click or scan EU-EC-10008366607 | | 2021-04-20 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19534 | click or scan EU-EC-10008365964 | | 2021-04-20 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19535 | click or scan EU-EC-10008364678 | | 2021-04-20 | Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (10d - Fatal - **Results in Death**), Cerebrovascular accident (10d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 19536 | click or scan EU-EC-10008364613 | | 2021-04-20 | Healthcare Professional | EEA | Not Specified | Female | COVID-19 (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19537 | click or scan EU-EC-10008366330 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19538 | click or scan EU-EC-10008366141 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19539 | click or scan EU-EC-10008366037 | | 2021-04-19 | Non Healthcare Professional | EEA | Not Specified | Female | Coronavirus infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19540 | click or scan EU-EC-10008365951 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19541 | click or scan EU-EC-10008365884 | | 2021-04-19 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - Intramuscular]) |
| 19542 | click or scan EU-EC-10008365560 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19543** | click or scan EU-EC-10008365532 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), LUCENTIS 10 MG/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE [RANIBIZUMAB] (S - Macular degeneration - Not applicable - [37d - n/a - n/a]) |
| **19544** | click or scan EU-EC-10008365506 | | 2021-04-19 | Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **19545** | click or scan EU-EC-10008365135 | | 2021-04-19 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19546** | click or scan EU-EC-10008364612 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19547** | click or scan EU-EC-10008364611 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (61h - Fatal - **Results in Death**), Dysphagia (3d - Unknown - Life Threatening, Other Medically Important Condition), Feeding disorder (3d - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19548** | click or scan EU-EC-10008364568 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19549** | click or scan EU-EC-10008364478 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19550** | click or scan EU-EC-10008364333 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19551** | click or scan EU-EC-10008363896 | | 2021-04-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Thrombosis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19552** | click or scan EU-EC-10008363895 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19553 | click or scan EU-EC-10008363876 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19554 | click or scan EU-EC-10008363737 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19555 | click or scan EU-EC-10008363534 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19556 | click or scan EU-EC-10008363466 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19557 | click or scan EU-EC-10008363457 | | 2021-04-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Not Recovered/Not Resolved - ), Condition aggravated (9d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (9d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Hypoxia (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological decompensation (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - ), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - ), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stroke in evolution (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19558 | click or scan EU-EC-10008363420 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Herpes zoster (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19559 | click or scan EU-EC-10008363038 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 19560 | click or scan EU-EC-10008362815 | | 2021-04-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal distension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Hypopnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19561 | click or scan EU-EC-10008362803 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19562 | click or scan EU-EC-10008362794 |  | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19563 | click or scan EU-EC-10008362309 |  | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular]) |
| 19564 | click or scan EU-EC-10008361710 |  | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 19565 | click or scan EU-EC-10008361708 |  | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory distress (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| 19566 | click or scan EU-EC-10008361629 |  | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac tamponade (n/a - Fatal - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | BRILIQUE [TICAGRELOR] (S - Thrombosis prophylaxis - Drug withdrawn - [n/a - 90mg - Oral]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Thrombosis prophylaxis - Drug withdrawn - [n/a - 75mg - Oral]), [WARFARIN SODIUM] (S - Atrial fibrillation - Drug withdrawn - [n/a - 2mg - Oral]) |
| 19567 | click or scan EU-EC-10008361585 |  | 2021-04-19 | Healthcare Professional | EEA | 18-64 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 19568 | click or scan EU-EC-10008361574 |  | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| 19569 | click or scan EU-EC-10008361559 |  | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular]) |
| 19570 | click or scan EU-EC-10008361554 |  | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haematoma (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 30ug - Intramuscular]), [FLUINDIONE] (S - Atrial fibrillation - Drug withdrawn - [n/a - n/a - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19571 | click or scan EU-EC-10008361521 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Female | Drug ineffective (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19572 | click or scan EU-EC-10008361519 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Male | Depressed level of consciousness (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19573 | click or scan EU-EC-10008361504 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (16d - Fatal - **Results in Death**), Vaccination failure (17d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 19574 | click or scan EU-EC-10008361469 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 19575 | click or scan EU-EC-10008361453 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19576 | click or scan EU-EC-10008361408 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [21d - .6mL - Intramuscular]) |
| 19577 | click or scan EU-EC-10008361393 | | 2021-04-19 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 19578 | click or scan EU-EC-10008361195 | | 2021-04-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**), Resuscitation (1d - Fatal - **Results in Death**), Seizure like phenomena (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 19579 | click or scan EU-EC-10008361069 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Male | Megacolon (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19580 | click or scan EU-EC-10008361023 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19581 | click or scan EU-EC-10008360989 | | 2021-04-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Activated partial thromboplastin time prolonged (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation), Epistaxis (n/a - Recovering/Resolving - ), Hypertension (n/a - Recovering/Resolving - ), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19582 | click or scan EU-EC-10008360947 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pulse abnormal (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19583 | click or scan EU-EC-10008360687 | | 2021-04-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19584 | click or scan EU-EC-10008360686 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19585 | click or scan EU-EC-10008360621 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cheyne-Stokes respiration (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Other Medically Important Condition), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19586 | click or scan EU-EC-10008360402 | | 2021-04-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19587 | click or scan EU-EC-10008360397 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Femoral neck fracture (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19588 | click or scan EU-EC-10008360396 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19589 | click or scan EU-EC-10008360394 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19590 | click or scan EU-EC-10008360301 | | 2021-04-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19591** | click or scan EU-EC-10008360300 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Unknown - ), Cardiomegaly (n/a - Unknown - ), Condition aggravated (n/a - Unknown - ), Contusion (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Ocular hyperaemia (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Productive cough (n/a - Unknown - ), Sepsis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19592** | click or scan EU-EC-10008360058 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**), Hypopnoea (2d - Unknown - Other Medically Important Condition), Unresponsive to stimuli (2d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19593** | click or scan EU-EC-10008360047 | | 2021-04-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Gastric haemorrhage (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19594** | click or scan EU-EC-10008359200 | | 2021-04-19 | Healthcare Professional | EEA | Not Specified | Female | Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19595** | click or scan EU-EC-10008358558 | | 2021-04-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **19596** | click or scan EU-EC-10008358533 | | 2021-04-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Influenza like illness (8d - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19597** | click or scan EU-EC-10008358485 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (5d - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (5d - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19598** | click or scan EU-EC-10008358398 | | 2021-04-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Brain stem stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **19599** | click or scan EU-EC-10008358308 | | 2021-04-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19600 | click or scan EU-EC-10008357693 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19601 | click or scan EU-EC-10008357692 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19602 | click or scan EU-EC-10008357691 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19603 | click or scan EU-EC-10008357689 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Areflexia (n/a - Fatal - **Results in Death**), Drooling (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19604 | click or scan EU-EC-10008357685 | | 2021-04-19 | Healthcare Professional | Non EEA | Not Specified | Male | Autoimmune disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19605 | click or scan EU-EC-10008357683 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19606 | click or scan EU-EC-10008357676 | | 2021-04-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19607 | click or scan EU-EC-10008357661 | | 2021-04-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19608 | click or scan EU-EC-10008357643 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19609 | click or scan EU-EC-10008355890 | | 2021-04-19 | Healthcare Professional | EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**, Life Threatening), Loss of consciousness (0d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19610 | click or scan EU-EC-10008355826 | | 2021-04-19 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Diarrhoea (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19611 | click or scan EU-EC-10008355603 | | 2021-04-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (0d - Recovered/Resolved - ), Off label use (0d - Recovered/Resolved - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19612 | click or scan EU-EC-10008355506 | | 2021-04-19 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19613 | click or scan EU-EC-10008354943 | | 2021-04-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19614 | click or scan EU-EC-10008354821 | | 2021-04-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aphasia (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Disorientation (n/a - Unknown - ), Encephalitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Other Medically Important Condition), Tumefactive multiple sclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19615 | click or scan EU-EC-10008354325 | | 2021-04-18 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19616 | click or scan EU-EC-10008354062 | | 2021-04-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19617 | click or scan EU-EC-10008354029 | | 2021-04-18 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19618 | click or scan EU-EC-10008353933 | | 2021-04-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19619 | click or scan EU-EC-10008352981 | | 2021-04-18 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19620 | click or scan EU-EC-10008352823 | | 2021-04-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19621 | click or scan EU-EC-10008351615 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19622 | click or scan EU-EC-10008351426 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19623 | click or scan EU-EC-10008351045 | | 2021-04-17 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 19624 | click or scan EU-EC-10008351043 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abnormal dreams (n/a - Unknown - **Results in Death**), Angina pectoris (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Depressed mood (n/a - Unknown - **Results in Death**), Depression (n/a - Unknown - **Results in Death**), Dizziness (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Hyperhidrosis (n/a - Unknown - **Results in Death**), Musculoskeletal chest pain (n/a - Unknown - **Results in Death**), Raynaud's phenomenon (n/a - Unknown - **Results in Death**), Seizure (n/a - Unknown - **Results in Death**), Weight decreased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19625 | click or scan EU-EC-10008351010 | | 2021-04-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Unknown - **Results in Death**), Myocardial infarction (3d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19626 | click or scan EU-EC-10008350989 | | 2021-04-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Lethargy (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19627 | click or scan EU-EC-10008350988 | | 2021-04-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (15d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dysarthria (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Peripheral ischaemia (n/a - Unknown - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombocytopenia (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19628 | click or scan EU-EC-10008350986 | | 2021-04-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19629 | click or scan EU-EC-10008350980 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Haematemesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19630 | click or scan EU-EC-10008350978 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (17d - Fatal - **Results in Death**), Pulmonary oedema (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), Tri-iodothyronine decreased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19631 | click or scan EU-EC-10008350560 | | 2021-04-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhage (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Hepatic vein thrombosis (n/a - Unknown - **Results in Death**), Hypoperfusion (n/a - Unknown - **Results in Death**), Jugular vein thrombosis (n/a - Unknown - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19632 | click or scan EU-EC-10008350144 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Death (3d - Fatal - **Results in Death**), Internal haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19633 | click or scan EU-EC-10008350006 | | 2021-04-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19634 | click or scan EU-EC-10008349801 | | 2021-04-17 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19635 | click or scan EU-EC-10008349612 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19636 | click or scan EU-EC-10008349509 | | 2021-04-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19637 | click or scan EU-EC-10008349376 | | 2021-04-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19638 | click or scan EU-EC-10008349346 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Infarction (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19639 | click or scan EU-EC-10008349162 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19640 | click or scan EU-EC-10008349152 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pain in extremity (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19641 | click or scan EU-EC-10008349146 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Neck mass (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19642 | click or scan EU-EC-10008348770 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Presyncope (1d - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (6d - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19643 | click or scan EU-EC-10008348303 | | 2021-04-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19644 | click or scan EU-EC-10008347795 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19645 | click or scan EU-EC-10008347776 | | 2021-04-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Contusion (n/a - Not Recovered/Not Resolved - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - **Results in Death**), Gastrointestinal haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**), Haematemesis (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (9d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19646 | click or scan EU-EC-10008347569 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19647 | click or scan EU-EC-10008347459 | | 2021-04-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (12d - Fatal - **Results in Death**), Embolism (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19648 | click or scan EU-EC-10008347077 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Embolism (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19649 | click or scan EU-EC-10008346947 | | 2021-04-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19650 | click or scan EU-EC-10008346866 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19651 | click or scan EU-EC-10008346865 | | 2021-04-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19652 | click or scan EU-EC-10008346723 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Gastric haemorrhage (n/a - Unknown - **Results in Death**), Pneumonia aspiration (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**), Respiratory distress (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19653 | click or scan EU-EC-10008346712 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19654 | click or scan EU-EC-10008346579 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Chest pain (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Sleep disorder (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19655 | click or scan EU-EC-10008345795 | | 2021-04-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19656 | click or scan EU-EC-10008345635 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Peripheral ischaemia (8d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19657 | click or scan EU-EC-10008345056 | | 2021-04-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19658 | click or scan EU-EC-10008344346 | | 2021-04-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Unknown - **Results in Death**, Disabling), Haemorrhagic stroke (n/a - Unknown - **Results in Death**, Disabling), Hypercoagulation (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19659 | click or scan EU-EC-10008344015 | | 2021-04-17 | Healthcare Professional | Non EEA | Not Specified | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19660 | click or scan EU-EC-10008344012 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19661 | click or scan EU-EC-10008343495 | | 2021-04-17 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19662 | click or scan EU-EC-10008343372 | | 2021-04-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Nasal congestion (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19663 | click or scan EU-EC-10008342155 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Unknown - **Results in Death**), Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Delirium (n/a - Not Recovered/Not Resolved - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**), Hot flush (n/a - Not Recovered/Not Resolved - **Results in Death**), Hyponatraemic syndrome (n/a - Fatal - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**), Suicide attempt (n/a - Unknown - **Results in Death**), Weight decreased (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19664 | click or scan EU-EC-10008342042 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Renal failure (3d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19665 | click or scan EU-EC-10008341474 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Unknown - **Results in Death**), Thrombosis (10d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19666 | click or scan EU-EC-10008341270 | | 2021-04-17 | Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 19667 | click or scan EU-EC-10008341266 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19668 | click or scan EU-EC-10008341254 | | 2021-04-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Lethargy (n/a - Recovered/Resolved - **Results in Death**), Pneumonia bacterial (3d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19669 | click or scan EU-EC-10008341251 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - **Results in Death**), Chest discomfort (n/a - Unknown - **Results in Death**), Coronary artery thrombosis (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - **Results in Death**), Pericardial haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19670 | click or scan EU-EC-10008341248 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19671 | click or scan EU-EC-10008341188 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Coronavirus infection - Not applicable - [n/a - n/a - n/a]) |
| 19672 | click or scan EU-EC-10008341127 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19673 | click or scan EU-EC-10008341088 | | 2021-04-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac failure (n/a - Not Recovered/Not Resolved - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Heart rate increased (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 19674 | click or scan EU-EC-10008341082 | | 2021-04-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Urinary bladder haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 19675 | click or scan EU-EC-10008340629 | | 2021-04-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19676 | click or scan EU-EC-10008340583 | | 2021-04-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Incontinence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paralysis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19677 | click or scan EU-EC-10008340566 | | 2021-04-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19678 | click or scan EU-EC-10008340089 | | 2021-04-17 | Healthcare Professional | EEA | More than 85 Years | Female | Sopor (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19679 | click or scan EU-EC-10008339975 | | 2021-04-17 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19680 | click or scan EU-EC-10008339938 | | 2021-04-17 | Healthcare Professional | EEA | More than 85 Years | Female | Foaming at mouth (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19681 | click or scan EU-EC-10008339890 | | 2021-04-17 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 19682 | click or scan EU-EC-10008339710 | | 2021-04-17 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal distension (10d - Fatal - **Results in Death**), Abdominal pain upper (10d - Fatal - **Results in Death**), Cough (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19683 | click or scan EU-EC-10008339596 | | 2021-04-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19684 | click or scan EU-EC-10008339460 | | 2021-04-17 | Healthcare Professional | EEA | More than 85 Years | Female | Loss of consciousness (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19685 | click or scan EU-EC-10008339459 | | 2021-04-17 | Healthcare Professional | EEA | More than 85 Years | Female | Dysphagia (17d - Fatal - **Results in Death**), Sopor (17d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 19686 | click or scan EU-EC-10008339295 | | 2021-04-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Blood pressure systolic increased (n/a - Unknown - ), Cerebral infarction (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Coma scale abnormal (n/a - Unknown - Other Medically Important Condition), Contusion (n/a - Unknown - ), Fall (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Respiratory paralysis (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 19687 | click or scan EU-EC-10008337357 | | 2021-04-17 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (7d - Fatal - **Results in Death**), Cerebral haemorrhage (7d - Fatal - **Results in Death**), Coma (7d - Fatal - **Results in Death**), Headache (7d - Fatal - **Results in Death**), Thrombocytopenia (7d - Fatal - **Results in Death**), Transverse sinus thrombosis (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]), [DIENOGEST, ETHINYLESTRADIOL, ETHINYLESTRADIOL, NORGESTIMATE] (S - Endometriosis - Drug withdrawn - [n/a - 1 {DF} - n/a]) |
| 19688 | click or scan EU-EC-10008336946 | | 2021-04-17 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19689 | click or scan EU-EC-10008338912 | | 2021-04-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19690 | click or scan EU-EC-10008338904 | | 2021-04-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19691 | click or scan EU-EC-10008338737 | | 2021-04-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Extra dose administered (1d - Recovered/Resolved - ), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19692 | click or scan EU-EC-10008338311 | | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19693 | click or scan EU-EC-10008338301 | | 2021-04-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary tract infection (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 19694 | click or scan EU-EC-10008338142 | | 2021-04-16 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral venous sinus thrombosis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]) |
| 19695 | click or scan EU-EC-10008337933 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19696 | click or scan EU-EC-10008337932 | | 2021-04-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19697 | click or scan EU-EC-10008337916 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19698 | click or scan EU-EC-10008337418 | | 2021-04-16 | Healthcare Professional | EEA | More than 85 Years | Female | Aphasia (19d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiplegia (19d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Somnolence (19d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19699 | click or scan EU-EC-10008336729 | | 2021-04-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19700 | click or scan EU-EC-10008336382 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19701 | click or scan EU-EC-10008336329 | | 2021-04-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19702 | click or scan EU-EC-10008336094 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Unresponsive to stimuli (1d - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19703 | click or scan EU-EC-10008335957 | | 2021-04-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19704 | click or scan EU-EC-10008335685 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (26d - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (26d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 19705 | click or scan EU-EC-10008335440 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (56d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (56d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (56d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19706 | click or scan EU-EC-10008335367 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic lymphocytic leukaemia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19707 | click or scan EU-EC-10008335265 | | 2021-04-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19708 | click or scan EU-EC-10008334866 | | 2021-04-16 | Healthcare Professional | EEA | 18-64 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 19709 | click or scan EU-EC-10008334735 | | 2021-04-16 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19710 | click or scan EU-EC-10008334694 |  | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 19711 | click or scan EU-EC-10008334618 |  | 2021-04-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 19712 | click or scan EU-EC-10008334399 |  | 2021-04-16 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 19713 | click or scan EU-EC-10008334350 |  | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (8d - Fatal - **Results in Death**) | VAXZEVRIA COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) SUSPENSION FOR INJECTION [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 19714 | click or scan EU-EC-10008334008 |  | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Quadriparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 19715 | click or scan EU-EC-10008333983 |  | 2021-04-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19716 | click or scan EU-EC-10008333980 |  | 2021-04-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19717 | click or scan EU-EC-10008333979 |  | 2021-04-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19718 | click or scan EU-EC-10008333978 |  | 2021-04-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19719 | click or scan EU-EC-10008333973 |  | 2021-04-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Chills (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Insomnia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19720 | click or scan EU-EC-10008333969 | | 2021-04-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19721 | click or scan EU-EC-10008333833 | | 2021-04-16 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19722 | click or scan EU-EC-10008333496 | | 2021-04-16 | Non Healthcare Professional | EEA | Not Specified | Female | Aphasia (n/a - Unknown - Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Pyrexia (1d - Unknown - ), SARS-CoV-2 test negative (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 19723 | click or scan EU-EC-10008333495 | | 2021-04-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 19724 | click or scan EU-EC-10008333030 | | 2021-04-16 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| 19725 | click or scan EU-EC-10008332903 | | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19726 | click or scan EU-EC-10008332844 | | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19727 | click or scan EU-EC-10008332820 | | 2021-04-16 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain upper (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 19728 | click or scan EU-EC-10008332776 | | 2021-04-16 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [24d - 1 {DF} - Intramuscular]) |
| 19729 | click or scan EU-EC-10008331936 | | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19730 | click or scan EU-EC-10008331797 | | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 19731 | click or scan EU-EC-10008331525 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19732 | click or scan EU-EC-10008331499 | | 2021-04-16 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19733 | click or scan EU-EC-10008331487 | | 2021-04-16 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19734 | click or scan EU-EC-10008331221 | | 2021-04-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Disorientation (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hypoxia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19735 | click or scan EU-EC-10008331011 | | 2021-04-16 | Healthcare Professional | EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19736 | click or scan EU-EC-10008329610 | | 2021-04-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19737 | click or scan EU-EC-10008329447 | | 2021-04-16 | Healthcare Professional | EEA | Not Specified | Male | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 19738 | click or scan EU-EC-10008329122 | | 2021-04-16 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19739 | click or scan EU-EC-10008329087 | | 2021-04-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Lung neoplasm malignant (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19740 | click or scan EU-EC-10008329056 | | 2021-04-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Disabling), Nausea (n/a - Unknown - Disabling), Retching (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19741 | click or scan EU-EC-10008328108 | | 2021-04-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal discomfort (n/a - Fatal - **Results in Death**), Arterial thrombosis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**), Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19742 | click or scan EU-EC-10008327753 | | 2021-04-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19743 | click or scan EU-EC-10008324737 | | 2021-04-16 | Healthcare Professional | EEA | 18-64 Years | Male | Headache (6h - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19744 | click or scan EU-EC-10008324724 | | 2021-04-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19745 | click or scan EU-EC-10008324681 | | 2021-04-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Anal incontinence (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Stupor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 19746 | click or scan EU-EC-10008324517 | | 2021-04-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Transplant (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19747 | click or scan EU-EC-10008324270 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 19748 | click or scan EU-EC-10008324242 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19749 | click or scan EU-EC-10008324074 | | 2021-04-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Haemorrhage (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19750** | click or scan EU-EC-10008324028 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19751** | click or scan EU-EC-10008324002 | | 2021-04-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Unknown - ), Candida infection (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Dysuria (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Renal failure (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown - ), White blood cell disorder (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19752** | click or scan EU-EC-10008323734 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19753** | click or scan EU-EC-10008323694 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **19754** | click or scan EU-EC-10008323596 | | 2021-04-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19755** | click or scan EU-EC-10008323156 | | 2021-04-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19756** | click or scan EU-EC-10008323081 | | 2021-04-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **19757** | click or scan EU-EC-10008321839 | | 2021-04-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **19758** | click or scan EU-EC-10008321695 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved - ), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic stroke (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19759** | click or scan EU-EC-10008321646 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), [GEMCITABINE] (S - Pancreatic carcinoma metastatic - Unknown - [n/a - 1000mg/m2 - Intravenous (not otherwise specified)]), [GEMCITABINE] (S - n/a - Unknown - [n/a - 1000mg/m2 - Intravenous (not otherwise specified)]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19760 | click or scan EU-EC-10008321365 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Male | Acute abdomen (n/a - Fatal - **Results in Death**), Thrombosis mesenteric vessel (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19761 | click or scan EU-EC-10008321171 | | 2021-04-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Aphasia (n/a - Unknown - ), Cerebrovascular accident (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Facial paresis (n/a - Unknown - ), Haematoma (n/a - Unknown - ), Hemiplegia (n/a - Not Recovered/Not Resolved - ), Nystagmus (n/a - Unknown - ), Patient uncooperative (n/a - Unknown - ), Posture abnormal (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19762 | click or scan EU-EC-10008320844 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Anaemia (n/a - Unknown - Other Medically Important Condition), Aortic stenosis (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Atelectasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrioventricular block complete (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood pressure fluctuation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**), Staphylococcal bacteraemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 19763 | click or scan EU-EC-10008320174 | | 2021-04-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 19764 | click or scan EU-EC-10008320171 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiopulmonary failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Unknown - Other Medically Important Condition), Dementia Alzheimer's type (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19765 | click or scan EU-EC-10008320063 | | 2021-04-15 | Non Healthcare Professional | EEA | Not Specified | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 19766 | click or scan EU-EC-10008320060 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Babinski reflex test (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiovascular disorder (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Miosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nervous system disorder (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19767 | click or scan EU-EC-10008320055 | | 2021-04-15 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening), Adrenocortical insufficiency acute (n/a - Fatal - **Results in Death**, Life Threatening), Calculus urinary (n/a - Fatal - **Results in Death**, Life Threatening), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening), Colitis ischaemic (n/a - Fatal - **Results in Death**, Life Threatening), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening), Coombs negative haemolytic anaemia (n/a - Fatal - **Results in Death**, Life Threatening), Explorative laparotomy (n/a - Fatal - **Results in Death**, Life Threatening), Gallbladder necrosis (n/a - Fatal - **Results in Death**, Life Threatening), Haematocrit decreased (n/a - Fatal - **Results in Death**, Life Threatening), Haemodynamic instability (n/a - Fatal - **Results in Death**, Life Threatening), Hepatic failure (n/a - Fatal - **Results in Death**, Life Threatening), Hepatic steatosis (n/a - Fatal - **Results in Death**, Life Threatening), Hydronephrosis (n/a - Fatal - **Results in Death**, Life Threatening), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Life Threatening), Intestinal congestion (n/a - Fatal - **Results in Death**, Life Threatening), Intestinal infarction (n/a - Fatal - **Results in Death**, Life Threatening), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Life Threatening), Kidney rupture (n/a - Fatal - **Results in Death**, Life Threatening), Lactic acidosis (n/a - Fatal - **Results in Death**, Life Threatening), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening), Pleural effusion (n/a - Fatal - **Results in Death**, Life Threatening), Portal vein occlusion (n/a - Fatal - **Results in Death**, Life Threatening), Red blood cell count decreased (n/a - Fatal - **Results in Death**, Life Threatening), Renal colic (n/a - Fatal - **Results in Death**, Life Threatening), Renal disorder (n/a - Fatal - **Results in Death**, Life Threatening), Renal tubular disorder (n/a - Fatal - **Results in Death**, Life Threatening), Renal vascular thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening), Splanchnic hypoperfusion (n/a - Fatal - **Results in Death**, Life Threatening), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Thrombosis mesenteric vessel (n/a - Fatal - **Results in Death**, Life Threatening), Venoocclusive liver disease (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19768 | click or scan EU-EC-10008319734 | | 2021-04-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypophagia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19769 | click or scan EU-EC-10008319457 | | 2021-04-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cold sweat (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Communication disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Musculoskeletal chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19770 | click or scan EU-EC-10008319093 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 19771 | click or scan EU-EC-10008319013 | | 2021-04-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19772 | click or scan EU-EC-10008318930 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19773 | click or scan EU-EC-10008318750 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19774** | click or scan EU-EC-10008318748 | | 2021-04-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Body temperature decreased (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Salivary hypersecretion (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19775** | click or scan EU-EC-10008318234 | | 2021-04-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19776** | click or scan EU-EC-10008318181 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Female | Peripheral artery thrombosis (n/a - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), [CEFTRIAXONE SODIUM] (S - Urinary tract infection - Not applicable - [n/a - n/a - Parenteral]) |
| **19777** | click or scan EU-EC-10008318141 | | 2021-04-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19778** | click or scan EU-EC-10008318138 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19779** | click or scan EU-EC-10008318134 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19780** | click or scan EU-EC-10008318128 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Female | Hypotension (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19781** | click or scan EU-EC-10008318127 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Metabolic acidosis (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19782** | click or scan EU-EC-10008318049 | | 2021-04-15 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19783** | click or scan EU-EC-10008318035 | | 2021-04-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19784** | click or scan EU-EC-10008318030 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [20d - 2 {DF} - Intramuscular]) |
| **19785** | click or scan EU-EC-10008318029 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [20d - 2 {DF} - Intramuscular]) |
| **19786** | click or scan EU-EC-10008318019 | | 2021-04-15 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **19787** | click or scan EU-EC-10008317998 | | 2021-04-15 | Non Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **19788** | click or scan EU-EC-10008317729 | | 2021-04-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (1d - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Refusal of treatment by patient (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19789** | click or scan EU-EC-10008317722 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19790** | click or scan EU-EC-10008317273 | | 2021-04-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19791** | click or scan EU-EC-10008317172 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (2d - Recovered/Resolved - ), Pulmonary embolism (30min - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Intramuscular]) |
| **19792** | click or scan EU-EC-10008316888 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ventricular tachycardia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **19793** | click or scan EU-EC-10008316876 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Male | Transient ischaemic attack (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19794** | click or scan EU-EC-10008316692 | | 2021-04-15 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypokinesia (n/a - Unknown - ), Mesenteric vascular insufficiency (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19795** | click or scan EU-EC-10008316678 | | 2021-04-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral artery thrombosis (0d - Fatal - **Results in Death**), Cerebral infarction (0d - Fatal - **Results in Death**), Cerebrovascular accident (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **19796** | click or scan EU-EC-10008316570 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Male | Cough (0d - Fatal - **Results in Death**), Upper gastrointestinal haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19797** | click or scan EU-EC-10008316020 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19798** | click or scan EU-EC-10008315965 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19799** | click or scan EU-EC-10008315930 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **19800** | click or scan EU-EC-10008314852 | | 2021-04-15 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **19801** | click or scan EU-EC-10008314834 | | 2021-04-15 | Healthcare Professional | EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Recovering/Resolving - ), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovering/Resolving - ), Somnolence (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **19802** | click or scan EU-EC-10008314666 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19803** | click or scan EU-EC-10008314660 | | 2021-04-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - ), Coordination abnormal (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown - ), Hallucination (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Intrusive thoughts (n/a - Unknown - ), Malaise (n/a - Unknown - ), Muscle twitching (n/a - Unknown - ), Pallor (n/a - Unknown - ), Psychomotor hyperactivity (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - Other Medically Important Condition), Tachyphrenia (n/a - Unknown - ), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (25h - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19804** | click or scan EU-EC-10008314625 | | 2021-04-15 | Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19805** | click or scan EU-EC-10008314083 | | 2021-04-15 | Healthcare Professional | EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Presyncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **19806** | click or scan EU-EC-10008313512 | | 2021-04-15 | Non Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **19807** | click or scan EU-EC-10008313265 | | 2021-04-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeling hot (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - Other Medically Important Condition), Rash macular (n/a - Unknown - ), Throat tightness (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **19808** | click or scan EU-EC-10008313072 | | 2021-04-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Coronary artery disease (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Type 2 diabetes mellitus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **19809** | click or scan EU-EC-10008312454 | | 2021-04-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19810** | click or scan EU-EC-10008312007 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19811** | click or scan EU-EC-10008312005 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19812** | click or scan EU-EC-10008311966 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19813 | click or scan EU-EC-10008311910 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19814 | click or scan EU-EC-10008311844 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 19815 | click or scan EU-EC-10008311735 | | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19816 | click or scan EU-EC-10008311715 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19817 | click or scan EU-EC-10008311671 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Lung infiltration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 19818 | click or scan EU-EC-10008311508 | | 2021-04-14 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Presyncope (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 19819 | click or scan EU-EC-10008311292 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19820 | click or scan EU-EC-10008311051 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19821 | click or scan EU-EC-10008311017 | | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Illness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19822 | click or scan EU-EC-10008310961 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Recovered/Resolved With Sequelae - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19823 | click or scan EU-EC-10008310854 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19824** | click or scan EU-EC-10008310711 | | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Communication disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19825** | click or scan EU-EC-10008310316 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Alanine aminotransferase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspartate aminotransferase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19826** | click or scan EU-EC-10008310070 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19827** | click or scan EU-EC-10008310013 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hepatic failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19828** | click or scan EU-EC-10008309671 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19829** | click or scan EU-EC-10008309564 | | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Agonal death struggle (2d - Unknown - Caused/Prolonged Hospitalisation), Areflexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Unknown - Caused/Prolonged Hospitalisation), Complication associated with device (n/a - Unknown - Caused/Prolonged Hospitalisation), Corneal reflex decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Device malfunction (n/a - Unknown - Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (2d - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Presyncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Unknown - Caused/Prolonged Hospitalisation), Pupillary reflex impaired (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Respiratory acidosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vena cava thrombosis (2d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19830** | click or scan EU-EC-10008309496 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19831** | click or scan EU-EC-10008309116 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19832 | click or scan EU-EC-10008309086 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19833 | click or scan EU-EC-10008308999 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (8d - Fatal - **Results in Death**), Confusional state (8d - Fatal - **Results in Death**), Decreased appetite (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 19834 | click or scan EU-EC-10008308016 | | 2021-04-14 | Healthcare Professional | Non EEA | Not Specified | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19835 | click or scan EU-EC-10008307740 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - ), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19836 | click or scan EU-EC-10008307494 | | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abscess limb (11d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Decreased activity (11d - Fatal - **Results in Death**), Groin abscess (11d - Fatal - **Results in Death**), Increased upper airway secretion (11d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19837 | click or scan EU-EC-10008307475 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Traumatic intracranial haemorrhage (4d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19838 | click or scan EU-EC-10008307474 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 19839 | click or scan EU-EC-10008306730 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19840 | click or scan EU-EC-10008306725 | | 2021-04-14 | Non Healthcare Professional | EEA | Not Specified | Female | Chills (n/a - Unknown - ), Headache (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 19841 | click or scan EU-EC-10008306721 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Female | Chromaturia (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19842 | click or scan EU-EC-10008306449 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [23d - 1 {DF} - Intramuscular]) |
| 19843 | click or scan EU-EC-10008306437 | | 2021-04-14 | Healthcare Professional | EEA | 18-64 Years | Male | Epistaxis (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Pancytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19844 | click or scan EU-EC-10008306370 | | 2021-04-14 | Healthcare Professional | EEA | 18-64 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 19845 | click or scan EU-EC-10008306351 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 1 {DF} - Intramuscular]) |
| 19846 | click or scan EU-EC-10008306336 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 19847 | click or scan EU-EC-10008306301 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [LEVOFLOXACIN] (S - Bronchitis - Not applicable - [7d - 500mg - Oral]) |
| 19848 | click or scan EU-EC-10008306300 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 19849 | click or scan EU-EC-10008306271 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 19850 | click or scan EU-EC-10008305869 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19851 | click or scan EU-EC-10008305700 | | 2021-04-14 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19852 | click or scan EU-EC-10008305639 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19853 | click or scan EU-EC-10008305047 | | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19854 | click or scan EU-EC-10008305021 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (1d - Fatal - **Results in Death**), Cognitive disorder (1d - Fatal - **Results in Death**), Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19855 | click or scan EU-EC-10008304505 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Haemoptysis (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19856 | click or scan EU-EC-10008303877 | | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - ), Eating disorder (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19857 | click or scan EU-EC-10008303777 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19858 | click or scan EU-EC-10008303662 | | 2021-04-14 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Extensive swelling of vaccinated limb (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Injection site erythema (n/a - Fatal - **Results in Death**, Life Threatening), Injection site pain (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19859 | click or scan EU-EC-10008303647 | | 2021-04-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Fatal - **Results in Death**), Fluid intake reduced (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19860 | click or scan EU-EC-10008303172 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Apathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradyphrenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased activity (n/a - Unknown - ), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation), Productive cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Other Medically Important Condition), Quadriparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urosepsis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19861** | click or scan EU-EC-10008303151 | | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Immune thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19862** | click or scan EU-EC-10008303075 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening), Cold sweat (n/a - Fatal - **Results in Death**, Life Threatening), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Malaise (n/a - Fatal - **Results in Death**, Life Threatening), Pharyngeal swelling (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19863** | click or scan EU-EC-10008302240 | | 2021-04-14 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (4d - Fatal - **Results in Death**), Pneumonia (4d - Fatal - **Results in Death**), Respiratory distress (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **19864** | click or scan EU-EC-10008302231 | | 2021-04-14 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (34d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19865** | click or scan EU-EC-10008302082 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19866** | click or scan EU-EC-10008302079 | | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19867** | click or scan EU-EC-10008302075 | | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **19868** | click or scan EU-EC-10008302011 | | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19869** | click or scan EU-EC-10008302008 | | 2021-04-14 | Healthcare Professional | EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19870** | click or scan EU-EC-10008301988 |  | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **19871** | click or scan EU-EC-10008301528 |  | 2021-04-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19872** | click or scan EU-EC-10008301154 |  | 2021-04-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19873** | click or scan EU-EC-10008300846 |  | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19874** | click or scan EU-EC-10008300784 |  | 2021-04-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (4d - Unknown - Caused/Prolonged Hospitalisation), Hypotension (4d - Unknown - Caused/Prolonged Hospitalisation), Nail injury (4d - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (4d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19875** | click or scan EU-EC-10008300649 |  | 2021-04-14 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | Full blood count abnormal (37d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19876** | click or scan EU-EC-10008300627 |  | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **19877** | click or scan EU-EC-10008300114 |  | 2021-04-14 | Healthcare Professional | EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **19878** | click or scan EU-EC-10008299756 |  | 2021-04-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disease recurrence (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19879** | click or scan EU-EC-10008299597 |  | 2021-04-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Coma (n/a - Unknown - Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19880** | click or scan EU-EC-10008298978 |  | 2021-04-14 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19881** | click or scan EU-EC-10008298885 |  | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Hyperkalaemia (n/a - Fatal - **Results in Death**), Metabolic acidosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [0d - .5mL - Intramuscular]) |
| **19882** | click or scan EU-EC-10008298833 |  | 2021-04-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - ), Dyspnoea exertional (n/a - Unknown - ), Dyspraxia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **19883** | click or scan EU-EC-10008298329 |  | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pancreatic carcinoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19884** | click or scan EU-EC-10008298327 |  | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19885** | click or scan EU-EC-10008298290 |  | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19886** | click or scan EU-EC-10008298066 |  | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19887** | click or scan EU-EC-10008297835 |  | 2021-04-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Clostridium difficile infection (n/a - Fatal - **Results in Death**), Headache (4d - Fatal - **Results in Death**), Hypoacusis (n/a - Fatal - **Results in Death**), Urinary retention (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **19888** | click or scan EU-EC-10008297833 |  | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [1d - n/a - n/a]), [ACENOCOUMAROL] (S - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]) |
| **19889** | click or scan EU-EC-10008297812 |  | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19890** | click or scan EU-EC-10008297688 |  | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Septic shock (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19891** | click or scan EU-EC-10008297616 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Hypoxia (1d - Not Recovered/Not Resolved - ), Pyrexia (1d - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **19892** | click or scan EU-EC-10008297558 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Craniocerebral injury (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19893** | click or scan EU-EC-10008297358 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | Bacterial infection (n/a - Unknown - ), Basilar artery occlusion (n/a - Fatal - **Results in Death**), Brain stem infarction (n/a - Fatal - **Results in Death**), Leukocytosis (n/a - Unknown - ), Shift to the left (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **19894** | click or scan EU-EC-10008297274 | | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Meningitis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **19895** | click or scan EU-EC-10008297232 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1440min - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure chronic (1440min - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (1440min - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1440min - Fatal - **Results in Death**), Dyspnoea (8640min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic disorder (1440min - Fatal - **Results in Death**), Septic shock (1440min - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (1440min - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (4320min - Fatal - **Results in Death**, Other Medically Important Condition), Weight increased (1440min - Fatal - **Results in Death**, Other Medically Important Condition), Weight increased (8640min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19896** | click or scan EU-EC-10008296602 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19897** | click or scan EU-EC-10008296592 | | 2021-04-13 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19898** | click or scan EU-EC-10008296562 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Unknown - ), Condition aggravated (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Emotional distress (n/a - Unknown - ), Hepatic cirrhosis (n/a - Unknown - ), Pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19899** | click or scan EU-EC-10008296457 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **19900** | click or scan EU-EC-10008296448 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19901 | click or scan EU-EC-10008296316 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19902 | click or scan EU-EC-10008296079 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Hemiplegia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 19903 | click or scan EU-EC-10008296064 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 19904 | click or scan EU-EC-10008296041 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| 19905 | click or scan EU-EC-10008295550 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Apnoea (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Heart rate irregular (n/a - Unknown - ), Hypophagia (n/a - Unknown - ), Illness (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Malaise (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 19906 | click or scan EU-EC-10008295394 | | 2021-04-13 | Healthcare Professional | EEA | 18-64 Years | Female | Atelectasis (n/a - Not Recovered/Not Resolved - ), Brain oedema (n/a - Not Recovered/Not Resolved - ), Cerebral venous sinus thrombosis (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coma (n/a - Not Recovered/Not Resolved - ), Death (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - ), Hepatic artery thrombosis (1d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hepatic perfusion disorder (n/a - Not Recovered/Not Resolved - ), Hepatic vein thrombosis (n/a - Not Recovered/Not Resolved - ), Hypoperfusion (n/a - Not Recovered/Not Resolved - ), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - ), Mydriasis (n/a - Not Recovered/Not Resolved - ), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - ), Pupils unequal (n/a - Not Recovered/Not Resolved - ), Renal vein thrombosis (1d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19907 | click or scan EU-EC-10008295118 | | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hallucination, visual (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Photophobia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Venous haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a]) |
| 19908 | click or scan EU-EC-10008294930 | | 2021-04-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Skin weeping (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19909** | click or scan<br>EU-EC-10008294439 | | 2021-04-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral artery occlusion (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemolytic uraemic syndrome (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic stroke (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **19910** | click or scan<br>EU-EC-10008294133 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19911 | click or scan<br>EU-EC-10008294093 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Feeling abnormal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), SHINGRIX [RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E, STIMULON, MONOPHOSPHORYL LIPID A] (S - Product used for unknown indication - Not applicable - [1 d - n/a - Intramuscular]), [INFLUENZA A VIRUS A/TEXAS/50/2012 X-223A (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA A VIRUS A/CALIFORNIA/7/2009 X-179A (H1N1) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA B VIRUS B/MASSACHUSETTS/2/2012 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA B VIRUS B/BRISBANE/60/2008 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED)] (S - Product used for unknown indication - Not applicable - [1 d - 1 {DF} - Intramuscular]), [PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 4, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 6B, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 9V, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 14, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 18C, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 19F, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 23F, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 33F, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 8, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 22F, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 20, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 19A, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 17F, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 15B, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 12F, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 11A, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 9N, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 7F, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 5, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 3, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 2, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 1, PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 10A, PNEUMOCOCCAL POLYSACCHARIDE VACCINE (23 VALENT)] (S - Product used for unknown indication - Not applicable - [1 d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19912 | click or scan EU-EC-10008294012 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19913 | click or scan EU-EC-10008294011 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Epilepsy (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19914 | click or scan EU-EC-10008294010 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Atrioventricular block (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Bradycardia (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiovascular disorder (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiration abnormal (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Rhythm idioventricular (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19915 | click or scan EU-EC-10008294009 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19916 | click or scan EU-EC-10008294008 | | 2021-04-13 | Healthcare Professional | EEA | Not Specified | Not Specified | General physical health deterioration (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19917 | click or scan EU-EC-10008294007 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19918 | click or scan EU-EC-10008294006 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Blood lactic acid increased (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Lactic acidosis (n/a - Fatal - **Results in Death**), Livedo reticularis (n/a - Fatal - **Results in Death**), Liver function test abnormal (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**), Sedation (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19919 | click or scan EU-EC-10008293920 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Erythema (n/a - Recovering/Resolving - **Results in Death**, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Meningism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 19920 | click or scan EU-EC-10008293889 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19921** | click or scan EU-EC-10008293815 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19922** | click or scan EU-EC-10008293763 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Anaphylactic reaction (0d - Fatal - **Results in Death**), Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **19923** | click or scan EU-EC-10008293713 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19924** | click or scan EU-EC-10008293538 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Intentional dose omission (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19925** | click or scan EU-EC-10008293437 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19926** | click or scan EU-EC-10008293335 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19927** | click or scan EU-EC-10008293328 | | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19928** | click or scan EU-EC-10008293118 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19929** | click or scan EU-EC-10008293024 | | 2021-04-13 | Healthcare Professional | EEA | 18-64 Years | Male | Lymphocytosis (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **19930** | click or scan EU-EC-10008292999 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19931 | click or scan EU-EC-10008292990 |  | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19932 | click or scan EU-EC-10008292978 |  | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 19933 | click or scan EU-EC-10008292970 |  | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Unevaluable event (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19934 | click or scan EU-EC-10008292921 |  | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | Blood pressure decreased (71d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19935 | click or scan EU-EC-10008292870 |  | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Ventricular arrhythmia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19936 | click or scan EU-EC-10008292850 |  | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Unknown - ), Hypernatraemia (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - ), Pallor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19937 | click or scan EU-EC-10008292835 |  | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19938 | click or scan EU-EC-10008292543 |  | 2021-04-13 | Healthcare Professional | EEA | 18-64 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19939 | click or scan EU-EC-10008292542 |  | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Retching (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19940** | click or scan EU-EC-10008292132 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Epilepsy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **19941** | click or scan EU-EC-10008292124 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **19942** | click or scan EU-EC-10008292114 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dementia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **19943** | click or scan EU-EC-10008292113 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **19944** | click or scan EU-EC-10008292103 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **19945** | click or scan EU-EC-10008292101 | | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **19946** | click or scan EU-EC-10008292100 | | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **19947** | click or scan EU-EC-10008292087 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (2d - Fatal - **Results in Death**), Epistaxis (2d - Fatal - **Results in Death**), Haematemesis (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **19948** | click or scan EU-EC-10008292064 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Gun shot wound (n/a - Fatal - **Results in Death**), Lung neoplasm malignant (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **19949** | click or scan EU-EC-10008292063 | | 2021-04-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **19950** | click or scan EU-EC-10008292055 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19951** | click or scan EU-EC-10008292054 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **19952** | click or scan EU-EC-10008292053 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Heart rate decreased (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19953** | click or scan EU-EC-10008292050 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19954** | click or scan EU-EC-10008292049 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Vital functions abnormal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19955** | click or scan EU-EC-10008292008 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Absence of immediate treatment response (n/a - Unknown - Caused/Prolonged Hospitalisation), Biliary colic (n/a - Unknown - Caused/Prolonged Hospitalisation), Cholelithiasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19956** | click or scan EU-EC-10008292005 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **19957** | click or scan EU-EC-10008291946 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure fluctuation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Not Recovered/Not Resolved - ), Dysphonia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Intentional product use issue (n/a - Not Recovered/Not Resolved - ), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulse abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Therapeutic product effect incomplete (n/a - Not Recovered/Not Resolved - ), Vaccination complication (n/a - Unknown - Caused/Prolonged Hospitalisation) | FIRDAPSE [AMIFAMPRIDINE] (S - Myasthenic syndrome - Dose not changed - [n/a - 10mg - Oral - More in ICSR]), FIRDAPSE [AMIFAMPRIDINE] (S - Myasthenic syndrome - Unknown - [n/a - 30mg - Oral - More in ICSR]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **19958** | click or scan EU-EC-10008291622 | | 2021-04-13 | Non Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **19959** | click or scan EU-EC-10008291516 | | 2021-04-13 | Healthcare Professional | EEA | Not Specified | Female | Confusional state (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19960 | click or scan EU-EC-10008291386 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19961 | click or scan EU-EC-10008291118 | | 2021-04-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Peripheral circulatory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19962 | click or scan EU-EC-10008291116 | | 2021-04-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - ), Chest pain (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 19963 | click or scan EU-EC-10008291113 | | 2021-04-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Peripheral circulatory failure (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 19964 | click or scan EU-EC-10008290730 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 19965 | click or scan EU-EC-10008290677 | | 2021-04-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site haematoma (2d - Recovered/Resolved - ), Myalgia (2d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19966 | click or scan EU-EC-10008290329 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (2d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19967 | click or scan EU-EC-10008290271 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19968 | click or scan EU-EC-10008290215 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19969 | click or scan EU-EC-10008289949 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 19970 | click or scan EU-EC-10008289934 | | 2021-04-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19971 | click or scan EU-EC-10008289912 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 19972 | click or scan EU-EC-10008289790 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Ischaemic stroke (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - ), Musculoskeletal pain (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Syncope (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 19973 | click or scan EU-EC-10008289629 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 19974 | click or scan EU-EC-10008289528 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 19975 | click or scan EU-EC-10008289338 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19976 | click or scan EU-EC-10008289336 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Feeling abnormal (1d - Unknown - Other Medically Important Condition), Nausea (1d - Unknown - Other Medically Important Condition), Pyrexia (1d - Unknown - Other Medically Important Condition), Vomiting (1d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19977 | click or scan EU-EC-10008289287 | | 2021-04-13 | Healthcare Professional | Non EEA | Not Specified | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19978 | click or scan EU-EC-10008289276 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 19979 | click or scan EU-EC-10008289274 | | 2021-04-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 19980 | click or scan EU-EC-10008289033 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **19981** | click or scan EU-EC-10008288563 | | 2021-04-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19982** | click or scan EU-EC-10008288554 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19983** | click or scan EU-EC-10008288055 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19984** | click or scan EU-EC-10008288047 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Apnoea (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **19985** | click or scan EU-EC-10008288023 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19986** | click or scan EU-EC-10008288018 | | 2021-04-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **19987** | click or scan EU-EC-10008287263 | | 2021-04-13 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **19988** | click or scan EU-EC-10008287235 | | 2021-04-13 | Healthcare Professional | EEA | More than 85 Years | Female | Cyanosis (1d - Fatal - **Results in Death**), Deep vein thrombosis (1d - Fatal - **Results in Death**), Oedema (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **19989** | click or scan EU-EC-10008286168 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary haemorrhage (1d - Fatal - **Results in Death**), Pulmonary thrombosis (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| **19990** | click or scan EU-EC-10008286045 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Meningitis herpes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 19991 | click or scan EU-EC-10008285217 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 19992 | click or scan EU-EC-10008284729 | | 2021-04-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |
| 19993 | click or scan EU-EC-10008284695 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 19994 | click or scan EU-EC-10008284688 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19995 | click or scan EU-EC-10008284656 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19996 | click or scan EU-EC-10008284589 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19997 | click or scan EU-EC-10008284586 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19998 | click or scan EU-EC-10008284564 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 19999 | click or scan EU-EC-10008284536 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 20000 | click or scan EU-EC-10008284510 | | 2021-04-12 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20001** | click or scan EU-EC-10008284455 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20002** | click or scan EU-EC-10008284387 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Thrombocytopenia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **20003** | click or scan EU-EC-10008284343 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **20004** | click or scan EU-EC-10008284062 | | 2021-04-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - Other Medically Important Condition), Erythema (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Irritability (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **20005** | click or scan EU-EC-10008283994 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20006** | click or scan EU-EC-10008283914 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Epilepsy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [35d - 2 {DF} - Intramuscular]) |
| **20007** | click or scan EU-EC-10008283893 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **20008** | click or scan EU-EC-10008283884 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **20009** | click or scan EU-EC-10008283797 | | 2021-04-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Body temperature increased (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20010** | click or scan EU-EC-10008283422 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Delirium (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20011 | click or scan EU-EC-10008283101 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20012 | click or scan EU-EC-10008283007 | | 2021-04-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20013 | click or scan EU-EC-10008282838 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous]) |
| 20014 | click or scan EU-EC-10008282794 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20015 | click or scan EU-EC-10008282204 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonitis (32d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20016 | click or scan EU-EC-10008282030 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 20017 | click or scan EU-EC-10008281593 | | 2021-04-12 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20018 | click or scan EU-EC-10008281392 | | 2021-04-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20019 | click or scan EU-EC-10008280860 | | 2021-04-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20020 | click or scan EU-EC-10008280789 | | 2021-04-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Viral infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20021** | click or scan EU-EC-10008280786 | | 2021-04-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Recovered/Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Myocardial infarction (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20022** | click or scan EU-EC-10008280690 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **20023** | click or scan EU-EC-10008280421 | | 2021-04-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20024** | click or scan EU-EC-10008280293 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20025** | click or scan EU-EC-10008280275 | | 2021-04-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20026** | click or scan EU-EC-10008279923 | | 2021-04-12 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **20027** | click or scan EU-EC-10008279828 | | 2021-04-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20028** | click or scan EU-EC-10008279734 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **20029** | click or scan EU-EC-10008279541 | | 2021-04-12 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20030** | click or scan EU-EC-10008279527 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20031** | click or scan EU-EC-10008279321 | | 2021-04-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Anuria (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyuria (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20032** | click or scan EU-EC-10008279225 | | 2021-04-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **20033** | click or scan EU-EC-10008278775 | | 2021-04-12 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **20034** | click or scan EU-EC-10008278657 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), RIVAROXABAN 15MG TABLET (S - Cardiac failure - Dose not changed - [n/a - 1 {DF} - n/a]) |
| **20035** | click or scan EU-EC-10008278648 | | 2021-04-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20036** | click or scan EU-EC-10008278011 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20037** | click or scan EU-EC-10008277559 | | 2021-04-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20038** | click or scan EU-EC-10008277166 | | 2021-04-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30min - n/a - Intramuscular]) |
| **20039** | click or scan EU-EC-10008277161 | | 2021-04-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20040** | click or scan EU-EC-10008277157 | | 2021-04-12 | Healthcare Professional | EEA | Not Specified | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (S - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]) |
| **20041** | click or scan EU-EC-10008277057 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Asthenia (n/a - Not Recovered/Not Resolved - ), Eastern Cooperative Oncology Group performance status worsened (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20042 | click or scan EU-EC-10008277055 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Hepatic cirrhosis (7d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Respiratory distress (7d - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 20043 | click or scan EU-EC-10008277051 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20044 | click or scan EU-EC-10008277013 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20045 | click or scan EU-EC-10008276919 | | 2021-04-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20046 | click or scan EU-EC-10008276902 | | 2021-04-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Irritability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 20047 | click or scan EU-EC-10008276864 | | 2021-04-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Unknown - Life Threatening), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - Life Threatening), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20048 | click or scan EU-EC-10008276814 | | 2021-04-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20049 | click or scan EU-EC-10008276811 | | 2021-04-12 | Healthcare Professional | EEA | 18-64 Years | Female | Epigastric discomfort (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 20050 | click or scan EU-EC-10008276584 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20051 | click or scan EU-EC-10008276456 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Male | General symptom (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20052** | click or scan EU-EC-10008276454 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20053** | click or scan EU-EC-10008276452 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20054** | click or scan EU-EC-10008276437 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Apathy (1d - Fatal - **Results in Death**), Confusional state (1d - Fatal - **Results in Death**), Coordination abnormal (1d - Fatal - **Results in Death**), Decreased appetite (2d - Fatal - **Results in Death**), Injection site inflammation (1d - Fatal - **Results in Death**), Injection site swelling (2d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20055** | click or scan EU-EC-10008276428 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Female | Bedridden (17d - Fatal - **Results in Death**), Fatigue (17d - Fatal - **Results in Death**), General physical health deterioration (7d - Fatal - **Results in Death**), Pneumonia aspiration (10d - Fatal - **Results in Death**), Productive cough (7d - Fatal - **Results in Death**), Pyrexia (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Vomiting (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20056** | click or scan EU-EC-10008276417 | | 2021-04-12 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20057** | click or scan EU-EC-10008275990 | | 2021-04-12 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral thrombosis (1d - Fatal - **Results in Death**), Depressed level of consciousness (1d - Fatal - **Results in Death**), Hemiplegia (1d - Fatal - **Results in Death**), Pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**), Thrombocytopenia (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20058** | click or scan EU-EC-10008275505 | | 2021-04-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **20059** | click or scan EU-EC-10008274859 | | 2021-04-12 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Gastrointestinal disorder (1d - Recovered/Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **20060** | click or scan EU-EC-10008274702 | | 2021-04-12 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **20061** | click or scan EU-EC-10008274226 | | 2021-04-11 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20062** | click or scan EU-EC-10008274141 | | 2021-04-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20063** | click or scan EU-EC-10008273941 | | 2021-04-11 | Non Healthcare Professional | EEA | Not Specified | Female | Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20064** | click or scan EU-EC-10008273928 | | 2021-04-11 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Unknown - **Results in Death**), Haemorrhagic stroke (21d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20065** | click or scan EU-EC-10008273838 | | 2021-04-11 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20066** | click or scan EU-EC-10008272109 | | 2021-04-10 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20067** | click or scan EU-EC-10008272022 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20068** | click or scan EU-EC-10008271128 | | 2021-04-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | Urinary bladder haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20069** | click or scan EU-EC-10008270810 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20070** | click or scan EU-EC-10008270806 | | 2021-04-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Arthralgia (n/a - Not Recovered/Not Resolved - **Results in Death**), Bone pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - **Results in Death**), Depression (n/a - Not Recovered/Not Resolved - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**), Dysphagia (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Epistaxis (n/a - Not Recovered/Not Resolved - **Results in Death**), Erythema (n/a - Not Recovered/Not Resolved - **Results in Death**), Eyelid oedema (n/a - Not Recovered/Not Resolved - **Results in Death**), Facial paralysis (n/a - Not Recovered/Not Resolved - **Results in Death**), Fall (n/a - Not Recovered/Not Resolved - **Results in Death**), Feeling hot (n/a - Not Recovered/Not Resolved - **Results in Death**), Hallucination (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypersensitivity (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypoaesthesia (n/a - Not Recovered/Not Resolved - **Results in Death**), Insomnia (n/a - Not Recovered/Not Resolved - **Results in Death**), Lip swelling (n/a - Not Recovered/Not Resolved - **Results in Death**), Muscular weakness (n/a - Not Recovered/Not Resolved - **Results in Death**), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Oral candidiasis (1d - Not Recovered/Not Resolved - **Results in Death**), Paraesthesia (n/a - Not Recovered/Not Resolved - **Results in Death**), Rectal haemorrhage (n/a - Recovering/Resolving - **Results in Death**), Restlessness (n/a - Not Recovered/Not Resolved - **Results in Death**), Skin lesion (n/a - Not Recovered/Not Resolved - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - **Results in Death**), Thirst (n/a - Not Recovered/Not Resolved - **Results in Death**), Tremor (n/a - Not Recovered/Not Resolved - **Results in Death**), Urinary tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**), Vision blurred (n/a - Not Recovered/Not Resolved - **Results in Death**), Visual impairment (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20071** | click or scan EU-EC-10008270712 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Injection site reaction (n/a - Recovered/Resolved - **Results in Death**), Pain in extremity (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20072** | click or scan EU-EC-10008270596 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20073** | click or scan EU-EC-10008270589 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20074** | click or scan EU-EC-10008269218 | | 2021-04-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute motor axonal neuropathy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20075** | click or scan EU-EC-10008268586 | | 2021-04-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | Back pain (n/a - Recovering/Resolving - **Results in Death**, Life Threatening), Fatigue (n/a - Recovering/Resolving - **Results in Death**, Life Threatening), Oral candidiasis (n/a - Recovering/Resolving - **Results in Death**, Life Threatening), Pyometra (n/a - Fatal - **Results in Death**, Life Threatening), Septic shock (n/a - Recovering/Resolving - **Results in Death**, Life Threatening), Skin depigmentation (n/a - Recovering/Resolving - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20076** | click or scan EU-EC-10008268433 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20077** | click or scan EU-EC-10008267682 | | 2021-04-10 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20078** | click or scan EU-EC-10008267109 | | 2021-04-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**), Suicide attempt (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20079** | click or scan EU-EC-10008266120 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20080** | click or scan EU-EC-10008265530 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20081** | click or scan EU-EC-10008265143 | | 2021-04-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20082** | click or scan EU-EC-10008264741 | | 2021-04-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20083** | click or scan EU-EC-10008263923 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20084** | click or scan EU-EC-10008263487 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20085** | click or scan EU-EC-10008263284 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20086** | click or scan EU-EC-10008263201 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20087** | click or scan EU-EC-10008262714 | | 2021-04-10 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20088** | click or scan EU-EC-10008262626 | | 2021-04-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | Embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20089** | click or scan EU-EC-10008262309 | | 2021-04-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Asthenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Blood glucose abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cognitive disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Delirium (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dysphagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hypophagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Orthostatic hypotension (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pneumonia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **20090** | click or scan EU-EC-10008262249 | | 2021-04-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Lethargy (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20091** | click or scan EU-EC-10008262076 | | 2021-04-10 | Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20092** | click or scan EU-EC-10008261488 | | 2021-04-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Balance disorder (n/a - Unknown - **Results in Death**), Cerebrovascular disorder (n/a - Not Recovered/Not Resolved - **Results in Death**), Cold sweat (n/a - Not Recovered/Not Resolved - **Results in Death**), Condition aggravated (n/a - Not Recovered/Not Resolved - **Results in Death**), Hyperhidrosis (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**), Pallor (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20093** | click or scan EU-EC-10008261412 | | 2021-04-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Embolic stroke (1d - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal infarct (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **20094** | click or scan EU-EC-10008261408 | | 2021-04-10 | Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20095** | click or scan EU-EC-10008261382 | | 2021-04-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (4d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20096 | click or scan EU-EC-10008261373 |  | 2021-04-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Budd-Chiari syndrome (5d - Fatal - **Results in Death**, Life Threatening), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Ovarian vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening), Renal vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20097 | click or scan EU-EC-10008260375 |  | 2021-04-10 | Healthcare Professional | EEA | More than 85 Years | Female | Peripheral embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 20098 | click or scan EU-EC-10008260287 |  | 2021-04-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20099 | click or scan EU-EC-10008260257 |  | 2021-04-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20100 | click or scan EU-EC-10008259858 |  | 2021-04-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dysarthria (36d - Fatal - **Results in Death**), Hemiparesis (36d - Fatal - **Results in Death**), Ischaemia (36d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 20101 | click or scan EU-EC-10008258544 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20102 | click or scan EU-EC-10008258525 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20103 | click or scan EU-EC-10008258351 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20104 | click or scan EU-EC-10008258083 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (1d - Fatal - **Results in Death**), Acute myocardial infarction (1d - Fatal - **Results in Death**), Acute respiratory distress syndrome (1d - Fatal - **Results in Death**), Acute respiratory failure (1d - Fatal - **Results in Death**), Bradycardia (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Cyanosis (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Haemoptysis (1d - Fatal - **Results in Death**), Leukocytosis (1d - Fatal - **Results in Death**), Lung infiltration (1d - Fatal - **Results in Death**), Metabolic acidosis (1d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**), Myocardial ischaemia (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**), Respiratory alkalosis (1d - Fatal - **Results in Death**), Respiratory symptom (1d - Fatal - **Results in Death**), Sepsis (1d - Fatal - **Results in Death**), Septic shock (1d - Fatal - **Results in Death**), Suspected COVID-19 (1d - Fatal - **Results in Death**), Tachypnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20105 | click or scan EU-EC-10008258018 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20106 | click or scan EU-EC-10008257993 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20107 | click or scan EU-EC-10008257899 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20108 | click or scan EU-EC-10008257764 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pain in extremity (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20109 | click or scan EU-EC-10008257763 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20110 | click or scan EU-EC-10008257488 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20111 | click or scan EU-EC-10008257474 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20112 | click or scan EU-EC-10008257253 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiogenic shock (1440min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20113 | click or scan EU-EC-10008257196 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20114 | click or scan EU-EC-10008257183 |  | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20115 | click or scan EU-EC-10008257062 |  | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Swelling (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20116 | click or scan EU-EC-10008257061 |  | 2021-04-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20117 | click or scan EU-EC-10008256943 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20118 | click or scan EU-EC-10008256907 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Hallucination, visual (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20119 | click or scan EU-EC-10008256861 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20120 | click or scan EU-EC-10008256844 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20121 | click or scan EU-EC-10008256700 |  | 2021-04-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation, Vaccination failure - Not applicable - [n/a - n/a - n/a]) |
| 20122 | click or scan EU-EC-10008255630 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Chest pain (2d - Not Recovered/Not Resolved - ), Nausea (2d - Not Recovered/Not Resolved - ), Syncope (1d - Not Recovered/Not Resolved - ), Vomiting (2d - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20123 | click or scan EU-EC-10008255617 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 20124 | click or scan EU-EC-10008255586 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20125** | click or scan EU-EC-10008255529 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20126** | click or scan EU-EC-10008255437 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20127** | click or scan EU-EC-10008255252 |  | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Choking (n/a - Unknown - ), Cough (n/a - Unknown - ), Dysphagia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Loss of consciousness (1d - Fatal - **Results in Death**), Posture abnormal (n/a - Unknown - ), Pulse absent (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20128** | click or scan EU-EC-10008255247 |  | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**), Respiratory distress (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20129** | click or scan EU-EC-10008255174 |  | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **20130** | click or scan EU-EC-10008255160 |  | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2 {DF} - Intramuscular]) |
| **20131** | click or scan EU-EC-10008255154 |  | 2021-04-09 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **20132** | click or scan EU-EC-10008255138 |  | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **20133** | click or scan EU-EC-10008255116 |  | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Female | Progressive supranuclear palsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20134** | click or scan EU-EC-10008255114 |  | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20135 | click or scan EU-EC-10008255087 | | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - .3mL - Intramuscular]) |
| 20136 | click or scan EU-EC-10008255056 | | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20137 | click or scan EU-EC-10008255004 | | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 20138 | click or scan EU-EC-10008254831 | | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]) |
| 20139 | click or scan EU-EC-10008254821 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20140 | click or scan EU-EC-10008254582 | | 2021-04-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20141 | click or scan EU-EC-10008254534 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20142 | click or scan EU-EC-10008254329 | | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (2d - Fatal - **Results in Death**), Condition aggravated (1d - Fatal - **Results in Death**), Feeling cold (1d - Fatal - **Results in Death**), Hypercholesterolaemia (1d - Fatal - **Results in Death**), Hypertension (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20143 | click or scan EU-EC-10008254253 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20144 | click or scan EU-EC-10008254236 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Urinary tract infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20145 | click or scan EU-EC-10008254138 | | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20146 | click or scan EU-EC-10008254137 | | 2021-04-09 | Healthcare Professional | EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - ), Cough (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral circulatory failure (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20147 | click or scan EU-EC-10008254119 | | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20148 | click or scan EU-EC-10008254083 | | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (17d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20149 | click or scan EU-EC-10008254062 | | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20150 | click or scan EU-EC-10008254026 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Crying (1wk - Unknown - ), Death (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Walking aid user (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20151 | click or scan EU-EC-10008254024 | | 2021-04-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Death (4d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Productive cough (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20152 | click or scan EU-EC-10008253661 | | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 20153 | click or scan EU-EC-10008253513 | | 2021-04-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20154 | click or scan EU-EC-10008253395 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20155 | click or scan EU-EC-10008253336 | | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - .3mL - Intramuscular]) |
| 20156 | click or scan EU-EC-10008253332 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20157 | click or scan EU-EC-10008253330 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20158 | click or scan EU-EC-10008253323 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20159 | click or scan EU-EC-10008253320 | | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 20160 | click or scan EU-EC-10008253313 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20161 | click or scan EU-EC-10008253055 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20162 | click or scan EU-EC-10008253040 | | 2021-04-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20163 | click or scan EU-EC-10008253035 | | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Chest pain (n/a - Not Recovered/Not Resolved - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20164 | click or scan EU-EC-10008253033 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20165 | click or scan EU-EC-10008252645 | | 2021-04-09 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20166 | click or scan EU-EC-10008251996 | | 2021-04-09 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20167 | click or scan EU-EC-10008251680 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20168 | click or scan EU-EC-10008251677 | | 2021-04-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20169 | click or scan EU-EC-10008250956 | | 2021-04-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening), Drug ineffective (n/a - Unknown - Life Threatening, Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20170 | click or scan EU-EC-10008250942 | | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20171 | click or scan EU-EC-10008250936 | | 2021-04-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20172 | click or scan EU-EC-10008250350 | | 2021-04-09 | Healthcare Professional | EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Varicose vein ruptured (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 20173 | click or scan EU-EC-10008250043 | | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Respiratory tract infection viral (n/a - Not Recovered/Not Resolved - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20174 | click or scan EU-EC-10008250033 | | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20175 | click or scan EU-EC-10008250031 | | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20176 | click or scan EU-EC-10008250022 | | 2021-04-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Pneumonia viral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20177 | click or scan EU-EC-10008249373 | | 2021-04-09 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cellulitis (n/a - Fatal - **Results in Death**), Erysipelas (n/a - Fatal - **Results in Death**), Thrombophlebitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20178 | click or scan EU-EC-10008249347 | | 2021-04-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20179 | click or scan EU-EC-10008248980 | | 2021-04-09 | Healthcare Professional | EEA | More than 85 Years | Female | Bedridden (n/a - Fatal - **Results in Death**), Dyspnoea (1a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (1a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20180 | click or scan EU-EC-10008248520 | | 2021-04-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20181 | click or scan EU-EC-10008248400 | | 2021-04-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Fatigue (n/a - Unknown - Other Medically Important Condition), Limb discomfort (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20182 | click or scan EU-EC-10008248378 | | 2021-04-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 20183 | click or scan EU-EC-10008248317 | | 2021-04-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 20184 | click or scan EU-EC-10008248151 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20185 | click or scan EU-EC-10008248145 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20186 | click or scan EU-EC-10008248132 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20187 | click or scan EU-EC-10008248121 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20188 | click or scan EU-EC-10008248118 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20189 | click or scan EU-EC-10008248113 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20190 | click or scan EU-EC-10008248111 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20191 | click or scan EU-EC-10008247959 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20192 | click or scan EU-EC-10008247958 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20193 | click or scan EU-EC-10008247957 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20194 | click or scan EU-EC-10008247956 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20195** | click or scan EU-EC-10008247955 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20196** | click or scan EU-EC-10008247954 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20197** | click or scan EU-EC-10008247953 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20198** | click or scan EU-EC-10008247952 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20199** | click or scan EU-EC-10008247951 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20200** | click or scan EU-EC-10008247950 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20201** | click or scan EU-EC-10008247949 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20202** | click or scan EU-EC-10008247948 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20203** | click or scan EU-EC-10008247947 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20204** | click or scan EU-EC-10008247946 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20205** | click or scan EU-EC-10008247945 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20206** | click or scan EU-EC-10008247944 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20207** | click or scan EU-EC-10008247943 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20208** | click or scan EU-EC-10008247942 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20209** | click or scan EU-EC-10008247941 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20210** | click or scan EU-EC-10008247940 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20211** | click or scan EU-EC-10008247939 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20212** | click or scan EU-EC-10008247938 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20213** | click or scan EU-EC-10008247937 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20214** | click or scan EU-EC-10008247936 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20215** | click or scan EU-EC-10008247935 |  | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20216** | click or scan EU-EC-10008247934 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20217** | click or scan EU-EC-10008247933 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20218** | click or scan EU-EC-10008247932 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20219** | click or scan EU-EC-10008247931 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20220** | click or scan EU-EC-10008247930 | | 2021-04-09 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20221** | click or scan EU-EC-10008247114 | | 2021-04-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **20222** | click or scan EU-EC-10008246817 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Diet refusal (n/a - Unknown - ), Hyponatraemia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **20223** | click or scan EU-EC-10008246807 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20224** | click or scan EU-EC-10008246806 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20225** | click or scan EU-EC-10008246804 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20226** | click or scan EU-EC-10008246792 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20227** | click or scan EU-EC-10008246764 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20228** | click or scan EU-EC-10008246729 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20229** | click or scan EU-EC-10008246724 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20230** | click or scan EU-EC-10008246709 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20231** | click or scan EU-EC-10008246707 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20232** | click or scan EU-EC-10008246701 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20233** | click or scan EU-EC-10008246698 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20234** | click or scan EU-EC-10008246689 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20235** | click or scan EU-EC-10008246683 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20236** | click or scan EU-EC-10008246674 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20237** | click or scan EU-EC-10008246671 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20238** | click or scan EU-EC-10008246655 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20239** | click or scan EU-EC-10008246654 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20240** | click or scan EU-EC-10008246650 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20241** | click or scan EU-EC-10008246617 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20242** | click or scan EU-EC-10008246602 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20243** | click or scan EU-EC-10008246597 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20244** | click or scan EU-EC-10008246576 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20245** | click or scan EU-EC-10008246573 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20246** | click or scan EU-EC-10008246417 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20247 | click or scan EU-EC-10008246411 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20248 | click or scan EU-EC-10008246406 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20249 | click or scan EU-EC-10008246404 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dry throat (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Eye movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Immobile (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - ), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Unknown - ), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20250 | click or scan EU-EC-10008246364 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20251 | click or scan EU-EC-10008246308 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20252 | click or scan EU-EC-10008246286 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20253 | click or scan EU-EC-10008246283 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20254 | click or scan EU-EC-10008246263 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20255 | click or scan EU-EC-10008246169 | | 2021-04-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20256 | click or scan EU-EC-10008246156 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (9d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (9d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (9d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (9d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (9d - Fatal - **Results in Death**, Other Medically Important Condition), Immediate post-injection reaction (9d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (9d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20257** | click or scan EU-EC-10008246152 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20258** | click or scan EU-EC-10008246092 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20259** | click or scan EU-EC-10008246062 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20260** | click or scan EU-EC-10008246058 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20261** | click or scan EU-EC-10008246055 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20262** | click or scan EU-EC-10008246042 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain herniation (1d - Fatal - **Results in Death**), Cerebral haemorrhage (1d - Fatal - **Results in Death**), Cerebral mass effect (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Neurological symptom (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **20263** | click or scan EU-EC-10008246029 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20264** | click or scan EU-EC-10008246021 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (2d - Unknown - ), Condition aggravated (2d - Unknown - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20265** | click or scan EU-EC-10008246019 | | 2021-04-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20266** | click or scan EU-EC-10008245944 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20267** | click or scan EU-EC-10008245921 | | 2021-04-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20268** | click or scan EU-EC-10008245913 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20269** | click or scan EU-EC-10008245894 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20270** | click or scan EU-EC-10008245874 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20271** | click or scan EU-EC-10008245872 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20272** | click or scan EU-EC-10008245838 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20273** | click or scan EU-EC-10008245670 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **20274** | click or scan EU-EC-10008245617 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR]), [ACENOCOUMAROL] (S - Deep vein thrombosis - Drug withdrawn - [n/a - 4mg - Oral]) |
| **20275** | click or scan EU-EC-10008245521 | | 2021-04-08 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **20276** | click or scan EU-EC-10008245516 | | 2021-04-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20277** | click or scan EU-EC-10008245273 | | 2021-04-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20278** | click or scan EU-EC-10008245131 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20279** | click or scan EU-EC-10008244750 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Memory impairment (n/a - Fatal - **Results in Death**), Nightmare (n/a - Fatal - **Results in Death**), Sleep disorder (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **20280** | click or scan EU-EC-10008244747 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiovascular disorder (1d - Unknown - Caused/Prolonged Hospitalisation), Cholecystitis (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (1d - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20281** | click or scan EU-EC-10008244746 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20282** | click or scan EU-EC-10008244735 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Gastrooesophageal reflux disease (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20283** | click or scan EU-EC-10008244731 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Incoherent (n/a - Unknown - Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20284** | click or scan EU-EC-10008244691 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20285** | click or scan EU-EC-10008244619 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | General physical health deterioration (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20286** | click or scan EU-EC-10008244427 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20287** | click or scan EU-EC-10008244419 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20288 | click or scan EU-EC-10008244415 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20289 | click or scan EU-EC-10008244414 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20290 | click or scan EU-EC-10008244363 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20291 | click or scan EU-EC-10008244362 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20292 | click or scan EU-EC-10008244273 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Eye movement disorder (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 20293 | click or scan EU-EC-10008244187 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20294 | click or scan EU-EC-10008244156 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20295 | click or scan EU-EC-10008244118 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Feeding tube user (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Hypophagia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20296 | click or scan EU-EC-10008243991 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20297 | click or scan EU-EC-10008243983 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20298** | click or scan EU-EC-10008243966 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20299** | click or scan EU-EC-10008243905 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20300** | click or scan EU-EC-10008243892 | | 2021-04-08 | Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20301** | click or scan EU-EC-10008243840 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20302** | click or scan EU-EC-10008243838 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **20303** | click or scan EU-EC-10008243738 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Cachexia (n/a - Fatal - **Results in Death**, Life Threatening), Dementia (n/a - Fatal - **Results in Death**, Life Threatening), Dysphagia (n/a - Fatal - **Results in Death**, Life Threatening), Odynophagia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20304** | click or scan EU-EC-10008243708 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20305** | click or scan EU-EC-10008243485 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1440min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20306** | click or scan EU-EC-10008243431 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (4d - Fatal - **Results in Death**), Decreased appetite (4d - Fatal - **Results in Death**), Dyspepsia (4d - Fatal - **Results in Death**), Fatigue (4d - Fatal - **Results in Death**), Myocardial infarction (4d - Fatal - **Results in Death**), Nausea (4d - Fatal - **Results in Death**), Pain (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20307** | click or scan EU-EC-10008243412 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20308** | click or scan EU-EC-10008243404 | | 2021-04-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - ), Cold sweat (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pain (n/a - Unknown - ), Paraesthesia (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20309 | click or scan EU-EC-10008243387 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20310 | click or scan EU-EC-10008243330 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Atrioventricular block complete (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 20311 | click or scan EU-EC-10008243313 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Female | Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 20312 | click or scan EU-EC-10008243303 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5uL - Intramuscular]) |
| 20313 | click or scan EU-EC-10008243250 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 20314 | click or scan EU-EC-10008243247 | | 2021-04-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 20315 | click or scan EU-EC-10008243138 | | 2021-04-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Tachycardia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 20316 | click or scan EU-EC-10008243064 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - 1 {DF} - Intramuscular]) |
| 20317 | click or scan EU-EC-10008242980 | | 2021-04-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | General physical health deterioration (3d - Unknown - ), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 20318 | click or scan EU-EC-10008242896 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Multi-organ disorder (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20319 | click or scan EU-EC-10008242869 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Polyuria (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20320 | click or scan EU-EC-10008242851 | | 2021-04-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 20321 | click or scan EU-EC-10008242760 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bowel movement irregularity (4d - Unknown - ), Death (1d - Fatal - **Results in Death**), Decreased appetite (4d - Unknown - ), Defaecation disorder (4d - Unknown - ), Dyspnoea (4d - Unknown - ), Nausea (4d - Unknown - ), Pain (4d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20322 | click or scan EU-EC-10008242759 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20323 | click or scan EU-EC-10008242712 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20324 | click or scan EU-EC-10008242654 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20325 | click or scan EU-EC-10008242642 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 20326 | click or scan EU-EC-10008242549 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20327 | click or scan EU-EC-10008242526 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Female | Bradycardia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 20328 | click or scan EU-EC-10008242407 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20329 | click or scan EU-EC-10008242238 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20330 | click or scan EU-EC-10008242208 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |
| 20331 | click or scan EU-EC-10008242140 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20332 | click or scan EU-EC-10008242063 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial rupture (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20333 | click or scan EU-EC-10008241894 | | 2021-04-08 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20334 | click or scan EU-EC-10008241756 | | 2021-04-08 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 20335 | click or scan EU-EC-10008241737 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20336 | click or scan EU-EC-10008241692 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20337 | click or scan EU-EC-10008241667 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20338 | click or scan EU-EC-10008241543 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Nightmare (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20339** | click or scan EU-EC-10008241511 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Confusional state (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dysphagia (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental impairment (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancreatitis (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20340** | click or scan EU-EC-10008241358 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20341** | click or scan EU-EC-10008241248 | | 2021-04-08 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20342** | click or scan EU-EC-10008241167 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20343** | click or scan EU-EC-10008241149 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20344** | click or scan EU-EC-10008241033 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20345** | click or scan EU-EC-10008240886 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (9d - Fatal - **Results in Death**), Diarrhoea (9d - Unknown - Other Medically Important Condition), Hypersomnia (9d - Unknown - Other Medically Important Condition), Hypophagia (9d - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **20346** | click or scan EU-EC-10008240884 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| **20347** | click or scan EU-EC-10008240439 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20348** | click or scan EU-EC-10008240432 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1440min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20349** | click or scan EU-EC-10008240304 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20350 | click or scan EU-EC-10008240191 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (25d - Unknown - Caused/Prolonged Hospitalisation), Hip fracture (n/a - Fatal - **Results in Death**), Pneumonia bacterial (n/a - Fatal - **Results in Death**), Poor peripheral circulation (25d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20351 | click or scan EU-EC-10008239986 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20352 | click or scan EU-EC-10008239949 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**), Cardiac failure congestive (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20353 | click or scan EU-EC-10008239924 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Altered state of consciousness (2d - Fatal - **Results in Death**), General physical health deterioration (2d - Fatal - **Results in Death**), Restlessness (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20354 | click or scan EU-EC-10008239830 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agonal death struggle (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20355 | click or scan EU-EC-10008239693 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20356 | click or scan EU-EC-10008239448 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20357 | click or scan EU-EC-10008239334 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 20358 | click or scan EU-EC-10008239171 | | 2021-04-08 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - Contraception - Dose not changed - [n/a - 1 {DF} - n/a]) |
| 20359 | click or scan EU-EC-10008238654 | | 2021-04-08 | Healthcare Professional | EEA | 18-64 Years | Female | Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20360** | click or scan EU-EC-10008238594 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20361** | click or scan EU-EC-10008238554 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20362** | click or scan EU-EC-10008238551 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20363** | click or scan EU-EC-10008238550 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20364** | click or scan EU-EC-10008238549 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20365** | click or scan EU-EC-10008238545 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20366** | click or scan EU-EC-10008238541 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20367** | click or scan EU-EC-10008238540 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20368** | click or scan EU-EC-10008238539 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20369** | click or scan EU-EC-10008238514 | | 2021-04-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Internal haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20370 | click or scan EU-EC-10008237212 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20371 | click or scan EU-EC-10008236730 | | 2021-04-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral circulatory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 20372 | click or scan EU-EC-10008236180 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atrioventricular block complete (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20373 | click or scan EU-EC-10008236106 | | 2021-04-08 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 20374 | click or scan EU-EC-10008235981 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20375 | click or scan EU-EC-10008235822 | | 2021-04-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20376 | click or scan EU-EC-10008235811 | | 2021-04-08 | Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (4d - Fatal - **Results in Death**), Malnutrition (4d - Fatal - **Results in Death**), Terminal state (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20377 | click or scan EU-EC-10008235049 | | 2021-04-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 20378 | click or scan EU-EC-10008234317 | | 2021-04-08 | Healthcare Professional | EEA | 18-64 Years | Female | Acute coronary syndrome (6d - Fatal - **Results in Death**), Aphasia (6d - Fatal - **Results in Death**), Coma (6d - Fatal - **Results in Death**), Disseminated intravascular coagulation (6d - Fatal - **Results in Death**), Haemorrhagic stroke (6d - Fatal - **Results in Death**), Hemiplegia (6d - Fatal - **Results in Death**), Pulmonary embolism (6d - Fatal - **Results in Death**), Thrombocytopenia (6d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 20379 | click or scan EU-EC-10008231692 | | 2021-04-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**), Hyperpyrexia (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 100ug - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20380** | click or scan EU-EC-10008233477 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Female | Bradycardia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20381** | click or scan EU-EC-10008233471 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20382** | click or scan EU-EC-10008233338 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20383** | click or scan EU-EC-10008233296 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20384** | click or scan EU-EC-10008233234 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20385** | click or scan EU-EC-10008233213 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Areflexia (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dysphagia (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Productive cough (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20386** | click or scan EU-EC-10008233037 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20387** | click or scan EU-EC-10008232828 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - Intramuscular]) |
| **20388** | click or scan EU-EC-10008232734 | | 2021-04-07 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **20389** | click or scan EU-EC-10008232619 | | 2021-04-07 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20390** | click or scan EU-EC-10008232347 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (761min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20391** | click or scan EU-EC-10008232203 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Infarction (n/a - Unknown - **Results in Death**), Pulmonary oedema (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| **20392** | click or scan EU-EC-10008232124 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20393** | click or scan EU-EC-10008232110 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20394** | click or scan EU-EC-10008232098 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20395** | click or scan EU-EC-10008232065 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20396** | click or scan EU-EC-10008232057 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20397** | click or scan EU-EC-10008231947 | | 2021-04-07 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **20398** | click or scan EU-EC-10008231944 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **20399** | click or scan EU-EC-10008231942 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20400 | click or scan EU-EC-10008231905 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20401 | click or scan EU-EC-10008231736 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20402 | click or scan EU-EC-10008230714 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 20403 | click or scan EU-EC-10008230507 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20404 | click or scan EU-EC-10008230367 | | 2021-04-07 | Healthcare Professional | EEA | 18-64 Years | Male | Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**), Herpes simplex hepatitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| 20405 | click or scan EU-EC-10008230343 | | 2021-04-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20406 | click or scan EU-EC-10008229744 | | 2021-04-07 | Healthcare Professional | EEA | Not Specified | Male | Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperpyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertriglyceridaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Serum ferritin abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20407 | click or scan EU-EC-10008229733 | | 2021-04-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dysphagia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20408 | click or scan EU-EC-10008229486 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 30ug - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20409 | click or scan EU-EC-10008228886 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Unknown - ), Chills (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Mass (n/a - Unknown - ), Muscle spasms (n/a - Unknown - ), Nasal mucosal disorder (n/a - Unknown - ), Pain (n/a - Unknown - ), Peripheral swelling (510min - Recovered/Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Renal failure (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20410 | click or scan EU-EC-10008228753 | | 2021-04-07 | Healthcare Professional | EEA | Not Specified | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20411 | click or scan EU-EC-10008228349 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20412 | click or scan EU-EC-10008228282 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20413 | click or scan EU-EC-10008228125 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20414 | click or scan EU-EC-10008227774 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20415 | click or scan EU-EC-10008227660 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20416 | click or scan EU-EC-10008227510 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20417 | click or scan EU-EC-10008227294 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 20418 | click or scan EU-EC-10008227164 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fluid intake reduced (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20419 | click or scan EU-EC-10008226694 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20420 | click or scan EU-EC-10008226355 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Malaise (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20421 | click or scan EU-EC-10008226281 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20422 | click or scan EU-EC-10008226245 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20423 | click or scan EU-EC-10008226244 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20424 | click or scan EU-EC-10008226054 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza like illness (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20425 | click or scan EU-EC-10008225433 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20426 | click or scan EU-EC-10008225355 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20427 | click or scan EU-EC-10008225340 | | 2021-04-07 | Healthcare Professional | EEA | 18-64 Years | Female | Contusion (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20428 | click or scan EU-EC-10008225339 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Constipation (n/a - Fatal - **Results in Death**), Faecal vomiting (n/a - Fatal - **Results in Death**), Gastric dilatation (n/a - Fatal - **Results in Death**), Intestinal obstruction (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20429 | click or scan EU-EC-10008225338 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20430 | click or scan EU-EC-10008225337 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiovascular disorder (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Troponin increased (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20431 | click or scan EU-EC-10008225283 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20432 | click or scan EU-EC-10008225053 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20433 | click or scan EU-EC-10008224627 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20434 | click or scan EU-EC-10008224577 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral artery occlusion (n/a - Fatal - **Results in Death**), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**), Neurological decompensation (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20435 | click or scan EU-EC-10008224469 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20436 | click or scan EU-EC-10008224081 | | 2021-04-07 | Non Healthcare Professional | EEA | More than 85 Years | Female | Heart rate increased (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20437 | click or scan EU-EC-10008223718 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), Embolic stroke (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 20438 | click or scan EU-EC-10008223639 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20439 | click or scan EU-EC-10008223447 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20440 | click or scan EU-EC-10008223403 | | 2021-04-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Unknown - ), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20441 | click or scan EU-EC-10008223376 | | 2021-04-07 | Healthcare Professional | EEA | Not Specified | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20442 | click or scan EU-EC-10008223181 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Chills (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Respiratory rate increased (n/a - Unknown - ), Restlessness (n/a - Unknown - ), Suspiciousness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20443 | click or scan EU-EC-10008223149 | | 2021-04-07 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Communication disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersomnia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20444 | click or scan EU-EC-10008222884 | | 2021-04-07 | Non Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20445 | click or scan EU-EC-10008222869 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20446 | click or scan EU-EC-10008222865 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20447 | click or scan EU-EC-10008222835 | | 2021-04-07 | Healthcare Professional | EEA | Not Specified | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20448 | click or scan EU-EC-10008222799 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20449 | click or scan EU-EC-10008222778 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20450 | click or scan EU-EC-10008222279 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Agranulocytosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Life Threatening), Neutropenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20451 | click or scan EU-EC-10008222013 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Erysipelas (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20452 | click or scan EU-EC-10008221973 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20453 | click or scan EU-EC-10008221729 | | 2021-04-07 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20454 | click or scan EU-EC-10008221674 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20455 | click or scan EU-EC-10008221404 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Female | Neonatal respiratory failure (30min - Fatal - **Results in Death**, Life Threatening), Seizure (30min - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 20456 | click or scan EU-EC-10008221135 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Atrial flutter (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac asthma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20457 | click or scan EU-EC-10008220624 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 20458 | click or scan EU-EC-10008219968 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Cough (n/a - Unknown - ), Gastroenteritis viral (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 20459 | click or scan EU-EC-10008219920 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 20460 | click or scan EU-EC-10008219878 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20461 | click or scan EU-EC-10008219785 | | 2021-04-07 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 20462 | click or scan EU-EC-10008219598 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest discomfort (n/a - Unknown - Life Threatening), Death (0d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Unknown - Life Threatening), Oxygen saturation decreased (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 20463 | click or scan EU-EC-10008219553 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - ), COVID-19 pneumonia (4d - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Influenza (n/a - Not Recovered/Not Resolved - ), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - ), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 20464 | click or scan EU-EC-10008219538 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (16d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 20465 | click or scan EU-EC-10008219534 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20466 | click or scan EU-EC-10008219511 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Left ventricular dilatation (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Other Medically Important Condition), Tissue discolouration (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20467 | click or scan EU-EC-10008219483 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Bedridden (2wk - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 20468 | click or scan EU-EC-10008219468 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (6d - Fatal - **Results in Death**, Disabling), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - Disabling), Muscular weakness (n/a - Not Recovered/Not Resolved - Disabling), Peripheral swelling (n/a - Not Recovered/Not Resolved - Disabling), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 20469 | click or scan EU-EC-10008219410 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20470 | click or scan EU-EC-10008219203 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Disorganised speech (n/a - Unknown - ), Headache (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Pallor (n/a - Unknown - ), Syncope (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20471** | click or scan EU-EC-10008219145 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cognitive disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20472** | click or scan EU-EC-10008219061 | | 2021-04-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20473** | click or scan EU-EC-10008219045 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Hallucination (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Status epilepticus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20474** | click or scan EU-EC-10008219030 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **20475** | click or scan EU-EC-10008219007 | | 2021-04-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20476** | click or scan EU-EC-10008218973 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | General physical health deterioration (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20477** | click or scan EU-EC-10008218939 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - 1 {DF} - n/a]) |
| **20478** | click or scan EU-EC-10008218900 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20479** | click or scan EU-EC-10008218858 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20480** | click or scan EU-EC-10008218836 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20481 | click or scan EU-EC-10008218763 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Panic attack (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20482 | click or scan EU-EC-10008218195 | | 2021-04-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20483 | click or scan EU-EC-10008217708 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20484 | click or scan EU-EC-10008217585 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20485 | click or scan EU-EC-10008216559 | | 2021-04-07 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20486 | click or scan EU-EC-10008216535 | | 2021-04-07 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral artery embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Coronary artery disease (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20487 | click or scan EU-EC-10008216533 | | 2021-04-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Kidney infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin laceration (n/a - Unknown - Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20488 | click or scan EU-EC-10008216492 | | 2021-04-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20489 | click or scan EU-EC-10008216096 | | 2021-04-07 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 20490 | click or scan EU-EC-10008215969 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20491 | click or scan EU-EC-10008215732 | | 2021-04-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**), Dementia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20492 | click or scan EU-EC-10008215069 | | 2021-04-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**), Cardiac failure (3d - Fatal - **Results in Death**), Hypotension (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20493 | click or scan EU-EC-10008213846 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | Influenza like illness (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20494 | click or scan EU-EC-10008213831 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Bedridden (21d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Hypophagia (21d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20495 | click or scan EU-EC-10008213693 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20496 | click or scan EU-EC-10008213539 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20497 | click or scan EU-EC-10008213500 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Arteriosclerosis (n/a - Fatal - **Results in Death**), Cardiac disorder (n/a - Fatal - **Results in Death**), Death (1440min - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20498 | click or scan EU-EC-10008213396 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20499 | click or scan EU-EC-10008213319 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20500 | click or scan EU-EC-10008213274 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20501** | click or scan EU-EC-10008213266 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20502** | click or scan EU-EC-10008213254 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **20503** | click or scan EU-EC-10008213228 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Failure to thrive (n/a - Fatal - **Results in Death**), Hypokalaemia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20504** | click or scan EU-EC-10008213204 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20505** | click or scan EU-EC-10008213201 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20506** | click or scan EU-EC-10008213035 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20507** | click or scan EU-EC-10008212935 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20508** | click or scan EU-EC-10008212855 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20509** | click or scan EU-EC-10008212818 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (2d - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [22d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20510** | click or scan EU-EC-10008212732 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20511** | click or scan EU-EC-10008212723 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown]) |
| **20512** | click or scan EU-EC-10008212677 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - .5mL - Intramuscular]) |
| **20513** | click or scan EU-EC-10008212633 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (3d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Dyspnoea exertional (3d - Fatal - **Results in Death**), Heart rate increased (3d - Fatal - **Results in Death**), Hyperhidrosis (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Respiratory rate increased (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20514** | click or scan EU-EC-10008212550 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20515** | click or scan EU-EC-10008212528 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20516** | click or scan EU-EC-10008212500 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **20517** | click or scan EU-EC-10008212345 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1440min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20518** | click or scan EU-EC-10008212333 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Incoherent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin exfoliation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20519** | click or scan EU-EC-10008211854 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20520 | click or scan EU-EC-10008211787 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20521 | click or scan EU-EC-10008211767 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20522 | click or scan EU-EC-10008211549 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20523 | click or scan EU-EC-10008211547 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20524 | click or scan EU-EC-10008211389 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Incoherent (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20525 | click or scan EU-EC-10008211353 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Lip swelling (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Swollen tongue (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20526 | click or scan EU-EC-10008211143 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20527 | click or scan EU-EC-10008211121 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20528 | click or scan EU-EC-10008211014 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| 20529 | click or scan EU-EC-10008210917 | | 2021-04-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Illness (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20530** | click or scan EU-EC-10008210875 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20531** | click or scan EU-EC-10008210827 | | 2021-04-06 | Healthcare Professional | Non EEA | Not Specified | Female | Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20532** | click or scan EU-EC-10008210809 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (1d - Fatal - **Results in Death**), Fatigue (1d - Unknown - ), Headache (1d - Unknown - ), Pain (1d - Unknown - ), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20533** | click or scan EU-EC-10008210687 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20534** | click or scan EU-EC-10008210665 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20535** | click or scan EU-EC-10008210664 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20536** | click or scan EU-EC-10008210660 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20537** | click or scan EU-EC-10008210651 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Altered state of consciousness (3d - Fatal - **Results in Death**), Bedridden (3d - Fatal - **Results in Death**), Decreased appetite (10d - Fatal - **Results in Death**), Fatigue (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20538** | click or scan EU-EC-10008210648 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Hallucination (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20539** | click or scan EU-EC-10008210647 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain lower (8d - Unknown - ), Pyrexia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20540** | click or scan EU-EC-10008210646 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20541** | click or scan EU-EC-10008210636 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20542** | click or scan EU-EC-10008210620 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Female | Food refusal (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20543** | click or scan EU-EC-10008210614 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20544** | click or scan EU-EC-10008210601 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20545** | click or scan EU-EC-10008210600 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20546** | click or scan EU-EC-10008210590 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **20547** | click or scan EU-EC-10008210586 | | 2021-04-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Staphylococcal sepsis (16d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20548** | click or scan EU-EC-10008210491 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Decubitus ulcer (n/a - Unknown - ), Disorientation (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Hypophagia (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Mental status changes (n/a - Unknown - ), Wound dehiscence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20549** | click or scan EU-EC-10008210224 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20550** | click or scan EU-EC-10008209916 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **20551** | click or scan EU-EC-10008209902 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20552 | click or scan EU-EC-10008209853 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20553 | click or scan EU-EC-10008209799 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 20554 | click or scan EU-EC-10008209788 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20555 | click or scan EU-EC-10008209617 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20556 | click or scan EU-EC-10008209612 | | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bacterial infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Bloody discharge (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Colostomy infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20557 | click or scan EU-EC-10008209604 | | 2021-04-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Eye disorder (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Neoplasm malignant (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20558 | click or scan EU-EC-10008209576 | | 2021-04-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20559 | click or scan EU-EC-10008209574 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20560 | click or scan EU-EC-10008209361 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20561 | click or scan EU-EC-10008209317 | | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Cardiac failure (1d - Fatal - **Results in Death**), Nausea (n/a - Unknown - ), Poor quality sleep (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20562 | click or scan EU-EC-10008208971 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20563** | click or scan EU-EC-10008208713 |  | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **20564** | click or scan EU-EC-10008208513 |  | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20565** | click or scan EU-EC-10008208512 |  | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20566** | click or scan EU-EC-10008208475 |  | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20567** | click or scan EU-EC-10008208435 |  | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20568** | click or scan EU-EC-10008208434 |  | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20569** | click or scan EU-EC-10008208311 |  | 2021-04-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening), Headache (n/a - Recovered/Resolved - ), Migraine (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved - ), Subarachnoid haemorrhage (n/a - Recovered/Resolved - ), Superior sagittal sinus thrombosis (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20570** | click or scan EU-EC-10008208292 |  | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20571** | click or scan EU-EC-10008208180 |  | 2021-04-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20572** | click or scan EU-EC-10008208103 |  | 2021-04-06 | Healthcare Professional | EEA | 18-64 Years | Male | Embolism (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20573** | click or scan EU-EC-10008207592 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20574** | click or scan EU-EC-10008207251 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sudden death (0d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20575** | click or scan EU-EC-10008206829 | | 2021-04-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20576** | click or scan EU-EC-10008206828 | | 2021-04-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20577** | click or scan EU-EC-10008206823 | | 2021-04-06 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Blood pressure decreased (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Laryngeal oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| **20578** | click or scan EU-EC-10008206819 | | 2021-04-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20579** | click or scan EU-EC-10008206516 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **20580** | click or scan EU-EC-10008206465 | | 2021-04-06 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**), Necrosis (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Wound (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20581** | click or scan EU-EC-10008206415 | | 2021-04-06 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20582** | click or scan EU-EC-10008206183 | | 2021-04-06 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20583 | click or scan EU-EC-10008205984 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 20584 | click or scan EU-EC-10008205901 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 20585 | click or scan EU-EC-10008205023 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 20586 | click or scan EU-EC-10008204978 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 20587 | click or scan EU-EC-10008203983 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20588 | click or scan EU-EC-10008203730 | | 2021-04-06 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous]) |
| 20589 | click or scan EU-EC-10008203303 | | 2021-04-06 | Healthcare Professional | EEA | More than 85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper respiratory tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 20590 | click or scan EU-EC-10008203289 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20591 | click or scan EU-EC-10008202776 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20592 | click or scan EU-EC-10008202431 | | 2021-04-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral thrombosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20593 | click or scan EU-EC-10008202250 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20594 | click or scan EU-EC-10008202195 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20595 | click or scan EU-EC-10008202165 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20596 | click or scan EU-EC-10008202162 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Leukaemia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 20597 | click or scan EU-EC-10008202137 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20598 | click or scan EU-EC-10008202105 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhagic stroke (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20599 | click or scan EU-EC-10008201965 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20600 | click or scan EU-EC-10008201917 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Left ventricular dysfunction (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20601 | click or scan EU-EC-10008201874 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20602 | click or scan EU-EC-10008201831 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**), Oedema (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20603 | click or scan EU-EC-10008201549 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Obesity (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20604** | click or scan EU-EC-10008201499 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20605** | click or scan EU-EC-10008201172 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Mental status changes (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20606** | click or scan EU-EC-10008201037 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20607** | click or scan EU-EC-10008200940 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (4d - Unknown - ), Condition aggravated (4d - Unknown - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **20608** | click or scan EU-EC-10008200932 | | 2021-04-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Airway patency device insertion (n/a - Fatal - **Results in Death**), Blood glucose increased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac assistance device user (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Mechanical ventilation (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20609** | click or scan EU-EC-10008200691 | | 2021-04-05 | Healthcare Professional | EEA | 65-85 Years | Female | Discomfort (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **20610** | click or scan EU-EC-10008199360 | | 2021-04-05 | Healthcare Professional | EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **20611** | click or scan EU-EC-10008198997 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Not Recovered/Not Resolved - Life Threatening), Communication disorder (n/a - Unknown - Life Threatening), Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Life Threatening), Inappropriate schedule of product administration (n/a - Unknown - ), Malaise (n/a - Unknown - Life Threatening), Off label use (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20612** | click or scan EU-EC-10008198405 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Burning sensation (12d - Fatal - **Results in Death**), Cardio-respiratory arrest (12d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Fatigue (12d - Fatal - **Results in Death**), Herpes zoster (5d - Fatal - **Results in Death**), Hypoaesthesia (1d - Fatal - **Results in Death**), Loss of consciousness (12d - Fatal - **Results in Death**), Myalgia (12d - Fatal - **Results in Death**), Neck pain (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**), Pyrexia (12d - Fatal - **Results in Death**), Rash pruritic (12d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20613** | click or scan EU-EC-10008198368 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20614** | click or scan EU-EC-10008198336 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20615** | click or scan EU-EC-10008198204 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20616** | click or scan EU-EC-10008198197 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20617** | click or scan EU-EC-10008198130 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20618** | click or scan EU-EC-10008198107 | | 2021-04-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20619** | click or scan EU-EC-10008198089 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung opacity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20620** | click or scan EU-EC-10008198088 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20621** | click or scan EU-EC-10008197653 | | 2021-04-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral embolism (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **20622** | click or scan EU-EC-10008197577 | | 2021-04-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (3d - Recovered/Resolved - ), Chills (4d - Recovered/Resolved - ), Fall (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Unknown - ), Hypertrophic cardiomyopathy (1d - Fatal - **Results in Death**), Myalgia (3d - Recovered/Resolved - ), Nausea (n/a - Unknown - ), Pain (3d - Recovered/Resolved - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20623** | click or scan EU-EC-10008197568 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20624** | click or scan EU-EC-10008197309 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Malaise (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20625** | click or scan EU-EC-10008197195 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20626** | click or scan EU-EC-10008195844 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20627** | click or scan EU-EC-10008195838 | | 2021-04-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Poor quality product administered (n/a - Unknown - ), Wrong technique in product usage process (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20628** | click or scan EU-EC-10008195117 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **20629** | click or scan EU-EC-10008195091 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20630** | click or scan EU-EC-10008195090 | | 2021-04-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Angina pectoris (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20631** | click or scan EU-EC-10008195057 | | 2021-04-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dementia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20632** | click or scan EU-EC-10008195044 | | 2021-04-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20633** | click or scan EU-EC-10008194479 | | 2021-04-05 | Healthcare Professional | EEA | More than 85 Years | Female | Blood creatinine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20634** | click or scan EU-EC-10008193965 | | 2021-04-05 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20635** | click or scan EU-EC-10008193962 | | 2021-04-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Diabetic ketoacidosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20636** | click or scan EU-EC-10008193659 | | 2021-04-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aspiration (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20637** | click or scan EU-EC-10008193650 | | 2021-04-05 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20638** | click or scan EU-EC-10008193350 | | 2021-04-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20639** | click or scan EU-EC-10008193332 | | 2021-04-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thalamic infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), White matter lesion (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20640** | click or scan EU-EC-10008193321 | | 2021-04-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Coronary artery occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20641** | click or scan EU-EC-10008193150 | | 2021-04-05 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **20642** | click or scan EU-EC-10008193052 | | 2021-04-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **20643** | click or scan EU-EC-10008191150 | | 2021-04-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myelitis transverse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20644** | click or scan EU-EC-10008191111 | | 2021-04-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20645** | click or scan EU-EC-10008191097 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiospasm (1d - Fatal - **Results in Death**, Disabling), Myocardial infarction (n/a - Unknown - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20646** | click or scan EU-EC-10008190619 | | 2021-04-03 | Non Healthcare Professional | Non EEA | Not Specified | Female | Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metastases to central nervous system (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **20647** | click or scan EU-EC-10008190596 | | 2021-04-03 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **20648** | click or scan EU-EC-10008189544 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Loss of consciousness (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - **Results in Death**), Urinary incontinence (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20649** | click or scan EU-EC-10008189531 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20650** | click or scan EU-EC-10008189004 | | 2021-04-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspepsia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20651** | click or scan EU-EC-10008188535 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20652** | click or scan EU-EC-10008188282 | | 2021-04-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (1d - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (1d - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **20653** | click or scan EU-EC-10008187978 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20654** | click or scan EU-EC-10008187349 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20655 | click or scan EU-EC-10008186911 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 20656 | click or scan EU-EC-10008186909 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - .5mL - Intravenous (not otherwise specified)]) |
| 20657 | click or scan EU-EC-10008186906 | | 2021-04-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Photophobia (n/a - Not Recovered/Not Resolved - **Results in Death**), Rash papular (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20658 | click or scan EU-EC-10008186880 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Platelet count decreased (10d - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Parenteral]) |
| 20659 | click or scan EU-EC-10008186855 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal oedema (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic vein thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Viral infection (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 20660 | click or scan EU-EC-10008186749 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Superior sagittal sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 20661 | click or scan EU-EC-10008186153 | | 2021-04-03 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 20662 | click or scan EU-EC-10008185811 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20663** | click or scan EU-EC-10008184654 | | 2021-04-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20664** | click or scan EU-EC-10008184523 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain upper (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Appendicitis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Night sweats (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presyncope (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Purpura (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20665** | click or scan EU-EC-10008184491 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **20666** | click or scan EU-EC-10008184467 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| **20667** | click or scan EU-EC-10008182592 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Partial seizures (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20668** | click or scan EU-EC-10008182544 | | 2021-04-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Unknown - **Results in Death**), Hypoxia (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Right ventricular dysfunction (n/a - Unknown - **Results in Death**), Seizure (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20669** | click or scan EU-EC-10008181809 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Colitis ischaemic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nodule (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20670** | click or scan EU-EC-10008181640 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20671** | click or scan EU-EC-10008180595 | | 2021-04-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20672** | click or scan EU-EC-10008180213 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20673** | click or scan EU-EC-10008180163 | | 2021-04-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebellar haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Intracranial haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20674** | click or scan EU-EC-10008180026 | | 2021-04-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **20675** | click or scan EU-EC-10008179332 | | 2021-04-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **20676** | click or scan EU-EC-10008179291 | | 2021-04-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (40d - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Insomnia (n/a - Unknown - **Results in Death**), Nausea (n/a - Unknown - **Results in Death**), Ocular discomfort (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **20677** | click or scan EU-EC-10008179169 | | 2021-04-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Joint swelling (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20678** | click or scan EU-EC-10008178257 | | 2021-04-03 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20679** | click or scan EU-EC-10008178231 | | 2021-04-03 | Healthcare Professional | EEA | More than 85 Years | Female | Extradural haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20680** | click or scan EU-EC-10008178197 | | 2021-04-03 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20681** | click or scan EU-EC-10008178036 | | 2021-04-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20682 | click or scan EU-EC-10008178028 | | 2021-04-03 | Healthcare Professional | EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 20683 | click or scan EU-EC-10008177529 | | 2021-04-03 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20684 | click or scan EU-EC-10008177302 | | 2021-04-03 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20685 | click or scan EU-EC-10008177139 | | 2021-04-03 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 20686 | click or scan EU-EC-10008176856 | | 2021-04-03 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20687 | click or scan EU-EC-10008176840 | | 2021-04-03 | Healthcare Professional | EEA | More than 85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dependent rubor (n/a - Fatal - **Results in Death**), Increased bronchial secretion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rhinorrhoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20688 | click or scan EU-EC-10008176823 | | 2021-04-03 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20689 | click or scan EU-EC-10008176604 | | 2021-04-03 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 20690 | click or scan EU-EC-10008176558 | | 2021-04-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20691 | click or scan EU-EC-10008176423 | | 2021-04-03 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20692 | click or scan EU-EC-10008176369 | | 2021-04-03 | Healthcare Professional | EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 20693 | click or scan EU-EC-10008176263 | | 2021-04-03 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20694 | click or scan EU-EC-10008175763 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20695 | click or scan EU-EC-10008175607 | | 2021-04-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20696 | click or scan EU-EC-10008175533 | | 2021-04-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arthralgia (7d - Fatal - **Results in Death**), Death (7d - Fatal - **Results in Death**), Influenza like illness (7d - Fatal - **Results in Death**), Pain in extremity (7d - Fatal - **Results in Death**), Syncope (7d - Fatal - **Results in Death**, Other Medically Important Condition), Tremor (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20697 | click or scan EU-EC-10008175531 | | 2021-04-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20698 | click or scan EU-EC-10008175359 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20699 | click or scan EU-EC-10008175150 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20700 | click or scan EU-EC-10008175073 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Systemic immune activation (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20701 | click or scan EU-EC-10008174929 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20702 | click or scan EU-EC-10008174739 | | 2021-04-02 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20703 | click or scan EU-EC-10008174692 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20704 | click or scan EU-EC-10008174637 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20705 | click or scan EU-EC-10008174581 | | 2021-04-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Malaise (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20706 | click or scan EU-EC-10008174444 | | 2021-04-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Platelet count decreased (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20707 | click or scan EU-EC-10008174421 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20708 | click or scan EU-EC-10008174251 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20709 | click or scan EU-EC-10008174129 | | 2021-04-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Feeling abnormal (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20710 | click or scan EU-EC-10008174060 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (2d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (2d - Fatal - **Results in Death**), Pulse absent (2d - Fatal - **Results in Death**), Pulseless electrical activity (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20711 | click or scan EU-EC-10008174058 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20712 | click or scan EU-EC-10008173894 | | 2021-04-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20713 | click or scan EU-EC-10008173538 | | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 20714 | click or scan EU-EC-10008173326 | | 2021-04-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute abdomen (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Gastrostomy (n/a - Fatal - **Results in Death**), Hypoglycaemia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20715 | click or scan EU-EC-10008173192 | | 2021-04-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20716 | click or scan EU-EC-10008173171 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose increased (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic encephalopathy (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20717 | click or scan EU-EC-10008173146 | | 2021-04-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiovascular disorder (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20718 | click or scan EU-EC-10008173134 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20719 | click or scan EU-EC-10008172993 | | 2021-04-02 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal heart rate abnormal (n/a - Unknown - Other Medically Important Condition), Foetal movement disorder (n/a - Unknown - Other Medically Important Condition), Syndactyly (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| 20720 | click or scan EU-EC-10008172916 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20721 | click or scan EU-EC-10008172900 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Fatal - **Results in Death**), Subdural haematoma (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20722 | click or scan EU-EC-10008172773 | | 2021-04-02 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - ), Incontinence (n/a - Not Recovered/Not Resolved - ), Muscular weakness (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20723 | click or scan EU-EC-10008171851 | | 2021-04-02 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Tinnitus (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20724 | click or scan EU-EC-10008171838 | | 2021-04-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Breath sounds abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypopnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory rate increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20725 | click or scan EU-EC-10008171834 | | 2021-04-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20726 | click or scan EU-EC-10008171649 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), International normalised ratio increased (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [FLUINDIONE] (S - Atrial fibrillation - Not applicable - [n/a - n/a - Oral]) |
| 20727 | click or scan EU-EC-10008171537 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20728 | click or scan EU-EC-10008171418 | | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 20729 | click or scan EU-EC-10008171413 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 20730 | click or scan EU-EC-10008171171 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20731 | click or scan EU-EC-10008171168 | | 2021-04-02 | Healthcare Professional | EEA | 18-64 Years | Male | Peripheral swelling (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20732** | click or scan EU-EC-10008171161 |  | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20733** | click or scan EU-EC-10008171001 |  | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20734** | click or scan EU-EC-10008170961 |  | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20735** | click or scan EU-EC-10008170858 |  | 2021-04-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Not Recovered/Not Resolved - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20736** | click or scan EU-EC-10008170852 |  | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | Intestinal obstruction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20737** | click or scan EU-EC-10008170790 |  | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20738** | click or scan EU-EC-10008170774 |  | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20739** | click or scan EU-EC-10008170686 |  | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20740** | click or scan EU-EC-10008170626 |  | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20741** | click or scan EU-EC-10008170625 |  | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | Lung disorder (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Tongue oedema (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20742** | click or scan EU-EC-10008170619 |  | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20743** | click or scan EU-EC-10008170535 | | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Recovering/Resolving - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (1d - Recovered/Resolved - **Results in Death**), Pyrexia (1d - Recovered/Resolved - **Results in Death**), Vomiting (1d - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20744** | click or scan EU-EC-10008170469 | | 2021-04-02 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **20745** | click or scan EU-EC-10008170308 | | 2021-04-02 | Non Healthcare Professional | EEA | More than 85 Years | Male | Ascites (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20746** | click or scan EU-EC-10008170302 | | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20747** | click or scan EU-EC-10008170201 | | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **20748** | click or scan EU-EC-10008170185 | | 2021-04-02 | Non Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20749** | click or scan EU-EC-10008170156 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20750** | click or scan EU-EC-10008170146 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20751** | click or scan EU-EC-10008170003 | | 2021-04-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Renal pain (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20752** | click or scan EU-EC-10008169543 | | 2021-04-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Headache (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20753** | click or scan EU-EC-10008169330 | | 2021-04-02 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute left ventricular failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Apnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - ), Cachexia (n/a - Not Recovered/Not Resolved - ), Hypopnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Language disorder (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20754** | click or scan EU-EC-10008169244 | | 2021-04-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20755** | click or scan EU-EC-10008169228 | | 2021-04-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20756** | click or scan EU-EC-10008169177 | | 2021-04-02 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20757** | click or scan EU-EC-10008169163 | | 2021-04-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Increased bronchial secretion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intestinal pseudo-obstruction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20758** | click or scan EU-EC-10008169158 | | 2021-04-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Aspiration (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - ), Left ventricular failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20759** | click or scan EU-EC-10008168260 | | 2021-04-02 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20760** | click or scan EU-EC-10008167467 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bronchitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20761** | click or scan EU-EC-10008167417 | | 2021-04-01 | Healthcare Professional | EEA | 18-64 Years | Female | Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - ), Meningitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ), Nervous system disorder (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20762 | click or scan EU-EC-10008167410 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20763 | click or scan EU-EC-10008167291 |  | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20764 | click or scan EU-EC-10008167275 |  | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20765 | click or scan EU-EC-10008167224 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20766 | click or scan EU-EC-10008167216 |  | 2021-04-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 20767 | click or scan EU-EC-10008167208 |  | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20768 | click or scan EU-EC-10008167199 |  | 2021-04-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 20769 | click or scan EU-EC-10008167175 |  | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20770 | click or scan EU-EC-10008167139 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Eye contusion (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20771 | click or scan EU-EC-10008167088 |  | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Contusion (n/a - Unknown - **Results in Death**, Life Threatening), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening), Haemorrhagic diathesis (n/a - Unknown - **Results in Death**, Life Threatening), Oedema peripheral (n/a - Unknown - **Results in Death**, Life Threatening), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20772 | click or scan EU-EC-10008167038 |  | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [24d - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20773** | click or scan EU-EC-10008167027 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial rupture (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]) |
| **20774** | click or scan EU-EC-10008166816 |  | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20775** | click or scan EU-EC-10008166776 |  | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20776** | click or scan EU-EC-10008166731 |  | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20777** | click or scan EU-EC-10008166673 |  | 2021-04-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20778** | click or scan EU-EC-10008166569 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20779** | click or scan EU-EC-10008166382 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Fatigue (2d - Unknown - ), Myalgia (2d - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20780** | click or scan EU-EC-10008166369 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20781** | click or scan EU-EC-10008166272 |  | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Unknown - Life Threatening), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20782** | click or scan EU-EC-10008165952 |  | 2021-04-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20783** | click or scan EU-EC-10008165939 |  | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20784** | click or scan EU-EC-10008165685 |  | 2021-04-01 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **20785** | click or scan EU-EC-10008165609 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20786** | click or scan EU-EC-10008165536 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20787** | click or scan EU-EC-10008165509 |  | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20788** | click or scan EU-EC-10008165243 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20789** | click or scan EU-EC-10008165204 |  | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20790** | click or scan EU-EC-10008165192 |  | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20791** | click or scan EU-EC-10008165173 |  | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Unknown - Life Threatening), Death (n/a - Fatal - **Results in Death**), Dysgeusia (n/a - Unknown - Life Threatening), Exposure to SARS-CoV-2 (n/a - Unknown - Life Threatening), Feeling abnormal (n/a - Unknown - Life Threatening), Gastrointestinal tract irritation (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Micturition urgency (n/a - Unknown - Life Threatening), Pain (n/a - Unknown - Life Threatening), Pollakiuria (n/a - Unknown - Life Threatening), Resuscitation (n/a - Unknown - Life Threatening), SARS-CoV-2 test negative (n/a - Unknown - Life Threatening), Somnolence (n/a - Unknown - Life Threatening), Syncope (n/a - Unknown - Life Threatening), Upper respiratory tract infection (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20792 | click or scan EU-EC-10008165163 | | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20793 | click or scan EU-EC-10008165104 | | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20794 | click or scan EU-EC-10008165103 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Gait inability (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20795 | click or scan EU-EC-10008165102 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20796 | click or scan EU-EC-10008165064 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20797 | click or scan EU-EC-10008164876 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dysstasia (2d - Fatal - **Results in Death**), Fall (2d - Fatal - **Results in Death**), Muscular weakness (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20798 | click or scan EU-EC-10008164820 | | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20799 | click or scan EU-EC-10008164806 | | 2021-04-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 20800 | click or scan EU-EC-10008164777 | | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Blood pressure fluctuation (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Heart rate irregular (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Throat tightness (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20801 | click or scan EU-EC-10008164753 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aggression (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20802 | click or scan EU-EC-10008164734 | | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Muscle rigidity (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20803 | click or scan EU-EC-10008164480 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20804 | click or scan EU-EC-10008164126 | | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20805 | click or scan EU-EC-10008164099 | | 2021-04-01 | Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20806 | click or scan EU-EC-10008164044 | | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20807 | click or scan EU-EC-10008164016 | | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20808 | click or scan EU-EC-10008163923 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20809 | click or scan EU-EC-10008163897 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20810 | click or scan EU-EC-10008163884 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20811 | click or scan EU-EC-10008163695 | | 2021-04-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20812** | click or scan EU-EC-10008163637 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20813** | click or scan EU-EC-10008163484 | | 2021-04-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal discomfort (7d - Unknown - Other Medically Important Condition), Malaise (7d - Unknown - Other Medically Important Condition), Pain (7d - Unknown - Other Medically Important Condition), Sudden death (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20814** | click or scan EU-EC-10008163478 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Mobility decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20815** | click or scan EU-EC-10008163472 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20816** | click or scan EU-EC-10008163087 | | 2021-04-01 | Healthcare Professional | EEA | 18-64 Years | Female | Brain oedema (n/a - Fatal - **Results in Death**), Intracranial pressure increased (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **20817** | click or scan EU-EC-10008163064 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Presyncope (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **20818** | click or scan EU-EC-10008163029 | | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Impaired work ability (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20819** | click or scan EU-EC-10008163017 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20820** | click or scan EU-EC-10008162620 | | 2021-04-01 | Healthcare Professional | EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20821** | click or scan EU-EC-10008161211 | | 2021-04-01 | Healthcare Professional | EEA | 65-85 Years | Male | Embolism (20min - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20822 | click or scan EU-EC-10008161044 | | 2021-04-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20823 | click or scan EU-EC-10008160836 | | 2021-04-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 20824 | click or scan EU-EC-10008160584 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 20825 | click or scan EU-EC-10008160576 | | 2021-04-01 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (5d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 20826 | click or scan EU-EC-10008159742 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Sepsis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 20827 | click or scan EU-EC-10008159675 | | 2021-04-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 20828 | click or scan EU-EC-10008159443 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 20829 | click or scan EU-EC-10008159410 | | 2021-04-01 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 20830 | click or scan EU-EC-10008158237 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Nausea (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20831 | click or scan EU-EC-10008158014 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20832** | click or scan EU-EC-10008157969 | | 2021-04-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20833** | click or scan EU-EC-10008157705 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Anal sphincter atony (2d - Fatal - **Results in Death**), Seizure (2d - Fatal - **Results in Death**), Sopor (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |
| **20834** | click or scan EU-EC-10008157330 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| **20835** | click or scan EU-EC-10008157241 | | 2021-04-01 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebellar stroke (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - n/a]) |
| **20836** | click or scan EU-EC-10008157160 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| **20837** | click or scan EU-EC-10008157048 | | 2021-04-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20838** | click or scan EU-EC-10008154861 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain upper (0d - Fatal - **Results in Death**), Coronary artery disease (0d - Fatal - **Results in Death**), Hypertensive heart disease (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **20839** | click or scan EU-EC-10008154677 | | 2021-04-01 | Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (15d - Fatal - **Results in Death**), Deep vein thrombosis (15d - Fatal - **Results in Death**), Dyspnoea (15d - Fatal - **Results in Death**), Pulmonary embolism (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **20840** | click or scan EU-EC-10008156967 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Faeces discoloured (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Terminal state (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20841** | click or scan EU-EC-10008156586 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20842** | click or scan EU-EC-10008156546 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dysphonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Restlessness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20843** | click or scan EU-EC-10008156506 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20844** | click or scan EU-EC-10008156458 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Respiratory distress (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20845** | click or scan EU-EC-10008156455 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20846** | click or scan EU-EC-10008156409 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden cardiac death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20847** | click or scan EU-EC-10008156345 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20848** | click or scan EU-EC-10008156305 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20849** | click or scan EU-EC-10008156258 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20850 | click or scan EU-EC-10008156200 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20851 | click or scan EU-EC-10008155899 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20852 | click or scan EU-EC-10008155884 | | 2021-03-31 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (1d - Fatal - **Results in Death**), Gastric cancer stage IV (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20853 | click or scan EU-EC-10008155829 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20854 | click or scan EU-EC-10008155697 | | 2021-03-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product use issue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20855 | click or scan EU-EC-10008155667 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bronchiolitis (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 20856 | click or scan EU-EC-10008155434 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - **Results in Death**), Systemic immune activation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| 20857 | click or scan EU-EC-10008155369 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20858 | click or scan EU-EC-10008155339 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20859 | click or scan EU-EC-10008155246 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiac arrest (n/a - Recovered/Resolved - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20860** | click or scan EU-EC-10008154485 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Lung neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20861** | click or scan EU-EC-10008154444 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **20862** | click or scan EU-EC-10008154216 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20863** | click or scan EU-EC-10008154089 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20864** | click or scan EU-EC-10008154071 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20865** | click or scan EU-EC-10008153945 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20866** | click or scan EU-EC-10008153720 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dementia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20867** | click or scan EU-EC-10008153202 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| **20868** | click or scan EU-EC-10008152975 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Disorientation (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Respiratory disorder (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [NIFEDIPINE] (S - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]) |
| **20869** | click or scan EU-EC-10008152972 | | 2021-03-31 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20870** | click or scan EU-EC-10008152656 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a - More in ICSR]) |
| **20871** | click or scan EU-EC-10008152645 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20872** | click or scan EU-EC-10008152538 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20873** | click or scan EU-EC-10008152531 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **20874** | click or scan EU-EC-10008152508 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20875** | click or scan EU-EC-10008152506 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Unknown - ), Pain (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Oral]) |
| **20876** | click or scan EU-EC-10008152502 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20877** | click or scan EU-EC-10008151600 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **20878** | click or scan EU-EC-10008151557 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **20879** | click or scan EU-EC-10008151402 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20880** | click or scan EU-EC-10008151302 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **20881** | click or scan EU-EC-10008151248 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20882** | click or scan EU-EC-10008150637 | | 2021-03-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20883** | click or scan EU-EC-10008150567 | | 2021-03-31 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **20884** | click or scan EU-EC-10008150556 | | 2021-03-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Epistaxis (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Retching (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20885** | click or scan EU-EC-10008150542 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20886** | click or scan EU-EC-10008150294 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20887** | click or scan EU-EC-10008149934 | | 2021-03-31 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate abnormal (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **20888** | click or scan EU-EC-10008149894 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Pancreatitis acute (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **20889** | click or scan EU-EC-10008149389 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20890** | click or scan EU-EC-10008149327 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **20891** | click or scan EU-EC-10008148944 | | 2021-03-31 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20892** | click or scan EU-EC-10008148939 | | 2021-03-31 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20893** | click or scan EU-EC-10008148938 | | 2021-03-31 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical condition abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20894** | click or scan EU-EC-10008148936 | | 2021-03-31 | Non Healthcare Professional | EEA | More than 85 Years | Female | Apathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Carotid artery occlusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20895** | click or scan EU-EC-10008148604 | | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **20896** | click or scan EU-EC-10008148551 | | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20897** | click or scan EU-EC-10008148493 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **20898** | click or scan EU-EC-10008148492 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **20899** | click or scan EU-EC-10008148091 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Angina pectoris (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20900 | click or scan EU-EC-10008148004 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20901 | click or scan EU-EC-10008147878 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20902 | click or scan EU-EC-10008147864 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20903 | click or scan EU-EC-10008147823 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20904 | click or scan EU-EC-10008147702 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20905 | click or scan EU-EC-10008147683 | | 2021-03-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Recovered/Resolved - ), Pain in extremity (n/a - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - n/a - n/a]) |
| 20906 | click or scan EU-EC-10008147455 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20907 | click or scan EU-EC-10008146771 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | SIMBRINZA 10 MG/ML + 2 MG/ML EYE DROPS, SUSPENSION [BRINZOLAMIDE, BRIMONIDINE TARTRATE] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Ophthalmic]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [BISOPROLOL FUMARATE] (S - Myocardial ischaemia - Not applicable - [n/a - 2.5mg - Oral]), [FUROSEMIDE] (S - Myocardial ischaemia - Not applicable - [n/a - 1 {DF} - Oral]), [LATANOPROST] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Ophthalmic]), [LEVOTHYROXINE SODIUM] (S - Hypothyroidism - Not applicable - [n/a - 1 {DF} - Oral]), [PRAVASTATIN SODIUM] (S - Dyslipidaemia - Not applicable - [n/a - 40mg - Oral]), [ZOPICLONE] (S - Product used for unknown indication - Not applicable - [n/a - 1 {DF} - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20908 | click or scan EU-EC-10008146684 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Hypertension (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Muscular weakness (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20909 | click or scan EU-EC-10008146547 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 20910 | click or scan EU-EC-10008146539 | | 2021-03-31 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 20911 | click or scan EU-EC-10008146432 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Supraventricular tachyarrhythmia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 20912 | click or scan EU-EC-10008146402 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - ), Syncope (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [10s - .5mL - Intramuscular]) |
| 20913 | click or scan EU-EC-10008146041 | | 2021-03-31 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 20914 | click or scan EU-EC-10008145981 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [10s - 1 {DF} - Intramuscular]) |
| 20915 | click or scan EU-EC-10008145901 | | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Female | Bereavement (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20916 | click or scan EU-EC-10008145777 | | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20917 | click or scan EU-EC-10008145133 | | 2021-03-31 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Swelling face (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20918 | click or scan EU-EC-10008144927 |  | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - ), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Hyperglycaemic hyperosmolar nonketotic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pelvic fracture (n/a - Unknown - Other Medically Important Condition), Pulmonary sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 20919 | click or scan EU-EC-10008144919 |  | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Facial paralysis (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Slow speech (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20920 | click or scan EU-EC-10008144866 |  | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20921 | click or scan EU-EC-10008144863 |  | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20922 | click or scan EU-EC-10008144536 |  | 2021-03-31 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20923 | click or scan EU-EC-10008144525 |  | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20924 | click or scan EU-EC-10008144512 |  | 2021-03-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Cough (1d - Fatal - **Results in Death**), Disability (1d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20925 | click or scan EU-EC-10008144171 |  | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Male | Acute kidney injury (1d - Fatal - **Results in Death**), Anuria (1d - Fatal - **Results in Death**), Dehydration (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20926 | click or scan EU-EC-10008144145 |  | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (5d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 20927 | click or scan EU-EC-10008143849 |  | 2021-03-31 | Healthcare Professional | EEA | More than 85 Years | Male | Arthralgia (1d - Fatal - **Results in Death**), Coma (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Pulmonary oedema (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Rales (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20928 | click or scan EU-EC-10008141885 |  | 2021-03-31 | Healthcare Professional | EEA | 65-85 Years | Female | Condition aggravated (1d - Fatal - **Results in Death**), Disorientation (1d - Fatal - **Results in Death**), Epilepsy (1d - Fatal - **Results in Death**), Hallucination (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 20929 | click or scan EU-EC-10008143190 |  | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20930 | click or scan EU-EC-10008143092 |  | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20931 | click or scan EU-EC-10008143005 |  | 2021-03-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20932 | click or scan EU-EC-10008142938 |  | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (1d - Fatal - **Results in Death**), Aortitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Arteritis coronary (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Inflammation (n/a - Unknown - ), Pain in jaw (n/a - Unknown - ), Pulse absent (1d - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20933 | click or scan EU-EC-10008142615 |  | 2021-03-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Delusion (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Mobility decreased (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20934 | click or scan EU-EC-10008142575 |  | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20935 | click or scan EU-EC-10008142561 |  | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20936 | click or scan EU-EC-10008142553 |  | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 20937 | click or scan EU-EC-10008142474 |  | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20938 | click or scan EU-EC-10008142439 |  | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **20939** | click or scan EU-EC-10008142389 | | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20940** | click or scan EU-EC-10008141937 | | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **20941** | click or scan EU-EC-10008141275 | | 2021-03-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20942** | click or scan EU-EC-10008141154 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20943** | click or scan EU-EC-10008141028 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20944** | click or scan EU-EC-10008140759 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Not Recovered/Not Resolved - ), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Hypopnoea (n/a - Not Recovered/Not Resolved - ), Pallor (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20945** | click or scan EU-EC-10008140731 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20946** | click or scan EU-EC-10008140391 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20947** | click or scan EU-EC-10008140382 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20948** | click or scan EU-EC-10008140334 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **20949** | click or scan EU-EC-10008140148 | | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20950** | click or scan EU-EC-10008140115 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20951** | click or scan EU-EC-10008140019 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **20952** | click or scan EU-EC-10008139785 | | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20953** | click or scan EU-EC-10008139758 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20954** | click or scan EU-EC-10008139602 | | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Feeling abnormal (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20955** | click or scan EU-EC-10008139494 | | 2021-03-30 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20956** | click or scan EU-EC-10008139261 | | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Chronic lymphocytic leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Unknown - ), Haemolytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - ), Hypoventilation (n/a - Unknown - Other Medically Important Condition), Jaundice (n/a - Unknown - ), Lymphocytosis (n/a - Unknown - ), Tremor (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **20957** | click or scan EU-EC-10008139256 | | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebellar haemorrhage (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **20958** | click or scan EU-EC-10008139066 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **20959** | click or scan EU-EC-10008138926 | | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Ear pain (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**), Pallor (n/a - Unknown - **Results in Death**), Pre-existing condition improved (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **20960** | click or scan EU-EC-10008138909 | | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Accidental overdose (1d - Fatal - **Results in Death**), Drug abuse (1d - Fatal - **Results in Death**), Toxicity to various agents (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **20961** | click or scan EU-EC-10008138830 | | 2021-03-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Dyspnoea (7d - Fatal - **Results in Death**), Haematemesis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (7d - Fatal - **Results in Death**), Pyrexia (7d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20962** | click or scan EU-EC-10008138796 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20963** | click or scan EU-EC-10008138795 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Pancytopenia (n/a - Fatal - **Results in Death**), Subdural haematoma (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **20964** | click or scan EU-EC-10008138792 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (29d - Fatal - **Results in Death**), C-reactive protein increased (29d - Fatal - **Results in Death**), Fatigue (31d - Fatal - **Results in Death**), Hypophagia (31d - Fatal - **Results in Death**), Muscle spasticity (31d - Fatal - **Results in Death**), Somnolence (31d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **20965** | click or scan EU-EC-10008138785 | | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **20966** | click or scan EU-EC-10008138774 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **20967** | click or scan EU-EC-10008138697 | | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Cerebrovascular accident (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 20968 | click or scan EU-EC-10008138579 |  | 2021-03-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20969 | click or scan EU-EC-10008138494 |  | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20970 | click or scan EU-EC-10008137699 |  | 2021-03-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain hypoxia (n/a - Unknown - Life Threatening), Cardiac fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Unknown - Life Threatening), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20971 | click or scan EU-EC-10008137698 |  | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 20972 | click or scan EU-EC-10008137693 |  | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 20973 | click or scan EU-EC-10008137682 |  | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20974 | click or scan EU-EC-10008137681 |  | 2021-03-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20975 | click or scan EU-EC-10008137663 |  | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac disorder (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Nasopharyngitis (0d - Fatal - **Results in Death**), Tremor (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20976 | click or scan EU-EC-10008137544 |  | 2021-03-30 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 20977 | click or scan EU-EC-10008137531 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20978 | click or scan EU-EC-10008137519 | | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20979 | click or scan EU-EC-10008137436 | | 2021-03-30 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 20980 | click or scan EU-EC-10008137263 | | 2021-03-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20981 | click or scan EU-EC-10008137254 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 20982 | click or scan EU-EC-10008136880 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 20983 | click or scan EU-EC-10008136879 | | 2021-03-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Not Recovered/Not Resolved - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Hypothermia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 20984 | click or scan EU-EC-10008136862 | | 2021-03-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastric cancer (n/a - Fatal - **Results in Death**), International normalised ratio increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20985 | click or scan EU-EC-10008136753 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20986 | click or scan EU-EC-10008136526 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20987 | click or scan EU-EC-10008136260 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 20988 | click or scan EU-EC-10008136058 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20989 | click or scan EU-EC-10008135724 | | 2021-03-30 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 20990 | click or scan EU-EC-10008135660 | | 2021-03-30 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 20991 | click or scan EU-EC-10008135472 | | 2021-03-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 20992 | click or scan EU-EC-10008135412 | | 2021-03-30 | Non Healthcare Professional | EEA | Not Specified | Female | Anti-platelet antibody (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 20993 | click or scan EU-EC-10008135269 | | 2021-03-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 20994 | click or scan EU-EC-10008135173 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20995 | click or scan EU-EC-10008135172 | | 2021-03-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (8d - Fatal - **Results in Death**), Coagulopathy (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 20996 | click or scan EU-EC-10008135171 | | 2021-03-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral ischaemia (10d - Fatal - **Results in Death**), Cerebrovascular accident (10d - Fatal - **Results in Death**), Coagulopathy (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 20997 | click or scan EU-EC-10008135170 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (3d - Fatal - **Results in Death**), Cardiac failure (3d - Fatal - **Results in Death**), Cardiogenic shock (1d - Fatal - **Results in Death**), Cardiomegaly (3d - Fatal - **Results in Death**), Lactic acidosis (3d - Fatal - **Results in Death**), Prohormone brain natriuretic peptide increased (3d - Fatal - **Results in Death**), Pulmonary oedema (1d - Fatal - **Results in Death**), Respiratory acidosis (3d - Fatal - **Results in Death**), Troponin T increased (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 20998 | click or scan EU-EC-10008134719 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 20999 | click or scan EU-EC-10008134714 | | 2021-03-30 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21000 | click or scan EU-EC-10008134710 | | 2021-03-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21001 | click or scan EU-EC-10008134707 | | 2021-03-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Coma scale abnormal (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Monoplegia (n/a - Fatal - **Results in Death**), Mydriasis (n/a - Fatal - **Results in Death**), Pupils unequal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21002 | click or scan EU-EC-10008134699 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Unknown - Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21003 | click or scan EU-EC-10008134608 | | 2021-03-30 | Healthcare Professional | EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21004 | click or scan EU-EC-10008134507 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1s - 1{DF} - Intramuscular]) |
| 21005 | click or scan EU-EC-10008134399 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21006 | click or scan EU-EC-10008134171 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21007 | click or scan EU-EC-10008133953 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21008 | click or scan EU-EC-10008133789 |  | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21009 | click or scan EU-EC-10008133654 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21010 | click or scan EU-EC-10008133335 |  | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21011 | click or scan EU-EC-10008133105 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21012 | click or scan EU-EC-10008132945 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| 21013 | click or scan EU-EC-10008132934 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| 21014 | click or scan EU-EC-10008132931 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21015 | click or scan EU-EC-10008132900 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Presyncope (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21016 | click or scan EU-EC-10008132576 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling drunk (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21017 | click or scan EU-EC-10008132501 |  | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21018 | click or scan EU-EC-10008132450 | | 2021-03-30 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Unknown]) |
| 21019 | click or scan EU-EC-10008132364 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening), General physical health deterioration (8d - Fatal - **Results in Death**, Life Threatening), Haemorrhage subcutaneous (8d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a]) |
| 21020 | click or scan EU-EC-10008131900 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multimorbidity (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21021 | click or scan EU-EC-10008131887 | | 2021-03-30 | Healthcare Professional | Non EEA | Not Specified | Male | Pneumonia viral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21022 | click or scan EU-EC-10008131741 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 21023 | click or scan EU-EC-10008130491 | | 2021-03-30 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21024 | click or scan EU-EC-10008128506 | | 2021-03-30 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21025 | click or scan EU-EC-10008129848 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Feeling hot (1d - Recovered/Resolved - ), Hypotension (n/a - Unknown - ), Pulseless electrical activity (n/a - Unknown - ), Seizure (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21026 | click or scan EU-EC-10008129819 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21027 | click or scan EU-EC-10008129800 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Conversion disorder (9d - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dysphagia (4d - Unknown - ), Fatigue (9d - Unknown - ), Pyrexia (9d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21028 | click or scan EU-EC-10008129778 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21029 | click or scan EU-EC-10008129768 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - ), Death (1d - Fatal - **Results in Death**), Dementia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diet refusal (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Restlessness (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21030 | click or scan EU-EC-10008129702 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21031 | click or scan EU-EC-10008129701 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21032 | click or scan EU-EC-10008129675 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21033 | click or scan EU-EC-10008129670 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cellulitis (7d - Fatal - **Results in Death**), Haemodynamic instability (7d - Fatal - **Results in Death**), Mental status changes (7d - Fatal - **Results in Death**), Postoperative wound infection (7d - Fatal - **Results in Death**), Pyrexia (7d - Fatal - **Results in Death**), Septic shock (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21034 | click or scan EU-EC-10008129627 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21035 | click or scan EU-EC-10008129431 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Injection site discomfort (1d - Recovered/Resolved - ), Loss of consciousness (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21036 | click or scan EU-EC-10008129423 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21037 | click or scan EU-EC-10008129319 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - ), Chills (n/a - Unknown - ), Condition aggravated (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21038 | click or scan EU-EC-10008129276 | | 2021-03-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21039 | click or scan EU-EC-10008129171 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 21040 | click or scan EU-EC-10008129120 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haematoma (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (S - Atrial fibrillation - Drug withdrawn - [619d - 5mg - Oral]) |
| 21041 | click or scan EU-EC-10008129043 | | 2021-03-29 | Healthcare Professional | EEA | Not Specified | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Elderly - Not applicable - [1d - n/a - n/a]) |
| 21042 | click or scan EU-EC-10008129027 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21043 | click or scan EU-EC-10008129013 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory distress (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular - More in ICSR]) |
| 21044 | click or scan EU-EC-10008128464 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21045 | click or scan EU-EC-10008128458 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21046 | click or scan EU-EC-10008128416 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21047 | click or scan EU-EC-10008128401 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Dizziness (5d - Unknown - Caused/Prolonged Hospitalisation), Nausea (5d - Unknown - Caused/Prolonged Hospitalisation), Vomiting (5d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21048 | click or scan EU-EC-10008128357 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atelectasis (n/a - Fatal - **Results in Death**), Axillary vein thrombosis (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21049 | click or scan EU-EC-10008128322 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dizziness (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21050 | click or scan EU-EC-10008128223 | | 2021-03-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21051 | click or scan EU-EC-10008128121 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21052 | click or scan EU-EC-10008128046 | | 2021-03-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (0d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21053 | click or scan EU-EC-10008127883 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21054 | click or scan EU-EC-10008127775 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21055 | click or scan EU-EC-10008127386 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21056 | click or scan EU-EC-10008127250 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Acute left ventricular failure (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21057 | click or scan EU-EC-10008127228 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21058 | click or scan EU-EC-10008127100 |  | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21059 | click or scan EU-EC-10008126922 |  | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Haematoma muscle (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (S - Anticoagulant therapy - Not applicable - [n/a - 5mg - Oral]) |
| 21060 | click or scan EU-EC-10008126838 |  | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21061 | click or scan EU-EC-10008126835 |  | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypertension (n/a - Unknown - **Results in Death**), Sense of oppression (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21062 | click or scan EU-EC-10008126750 |  | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Cardiovascular event prophylaxis - Not applicable - [n/a - 1 {DF} - Oral]), [BROMAZEPAM] (S - Mixed anxiety and depressive disorder - Not applicable - [n/a - 2 {DF} - Oral]), [FLUOXETINE HYDROCHLORIDE] (S - Mixed anxiety and depressive disorder - Not applicable - [n/a - 10mg - Oral]) |
| 21063 | click or scan EU-EC-10008126248 |  | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21064 | click or scan EU-EC-10008126227 |  | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**), Peripheral ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21065 | click or scan EU-EC-10008126154 |  | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21066 | click or scan EU-EC-10008126071 |  | 2021-03-29 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21067 | click or scan EU-EC-10008126018 |  | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21068 | click or scan EU-EC-10008126005 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21069 | click or scan EU-EC-10008126004 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21070 | click or scan EU-EC-10008125894 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21071 | click or scan EU-EC-10008125883 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21072 | click or scan EU-EC-10008125570 | | 2021-03-29 | Healthcare Professional | EEA | 18-64 Years | Male | Intestinal obstruction (n/a - Recovering/Resolving - **Results in Death**, Life Threatening), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [HYOSCINE] (S - n/a - n/a - [n/a - 1 {DF} - Transdermal]) |
| 21073 | click or scan EU-EC-10008125480 | | 2021-03-29 | Healthcare Professional | EEA | Not Specified | Female | Aneurysm ruptured (n/a - Unknown - Other Medically Important Condition), Arteriosclerosis (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Bronchiolitis (n/a - Unknown - Other Medically Important Condition), Cardiac hypertrophy (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Unknown - ), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Congestive hepatopathy (n/a - Unknown - Other Medically Important Condition), Emphysema (n/a - Unknown - ), Hepatic steatosis (n/a - Unknown - ), Hirsutism (n/a - Unknown - ), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Renal disorder (n/a - Unknown - ), Skin striae (n/a - Unknown - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21074 | click or scan EU-EC-10008125223 | | 2021-03-29 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebral haemorrhage (7d - Fatal - **Results in Death**), Malaise (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21075 | click or scan EU-EC-10008125188 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscle spasms (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21076 | click or scan EU-EC-10008124733 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (12d - Unknown - ), Cough (12d - Unknown - ), Death (1d - Fatal - **Results in Death**), Fatigue (12d - Unknown - ), Headache (12d - Unknown - ), Pain (12d - Unknown - ), Pyrexia (12d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21077 | click or scan EU-EC-10008124253 | | 2021-03-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21078** | click or scan EU-EC-10008124252 | | 2021-03-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **21079** | click or scan EU-EC-10008124086 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Hernia pain (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [GOSERELIN] (S - Prostate cancer metastatic - Dose not changed - [n/a - 10.8mg - n/a]) |
| **21080** | click or scan EU-EC-10008123686 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Death (3d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21081** | click or scan EU-EC-10008123493 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (2d - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Hyperphagia (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**), Weight increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21082** | click or scan EU-EC-10008123484 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21083** | click or scan EU-EC-10008123389 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **21084** | click or scan EU-EC-10008123369 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **21085** | click or scan EU-EC-10008123364 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **21086** | click or scan EU-EC-10008123360 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **21087** | click or scan EU-EC-10008123335 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21088** | click or scan EU-EC-10008123266 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Intestinal ischaemia (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| **21089** | click or scan EU-EC-10008123178 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21090** | click or scan EU-EC-10008123171 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **21091** | click or scan EU-EC-10008122914 | | 2021-03-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21092** | click or scan EU-EC-10008122664 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | Jaundice (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **21093** | click or scan EU-EC-10008122663 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **21094** | click or scan EU-EC-10008122644 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **21095** | click or scan EU-EC-10008122577 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Basal ganglia haemorrhage (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21096** | click or scan EU-EC-10008122496 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular]) |
| **21097** | click or scan EU-EC-10008121973 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21098 | click or scan EU-EC-10008121961 | | 2021-03-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21099 | click or scan EU-EC-10008121798 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21100 | click or scan EU-EC-10008121515 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21101 | click or scan EU-EC-10008121284 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21102 | click or scan EU-EC-10008121177 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Effusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (7d - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 21103 | click or scan EU-EC-10008121116 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21104 | click or scan EU-EC-10008121102 | | 2021-03-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Liver disorder (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21105 | click or scan EU-EC-10008121093 | | 2021-03-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21106 | click or scan EU-EC-10008120962 | | 2021-03-29 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21107 | click or scan EU-EC-10008120925 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 21108 | click or scan EU-EC-10008120327 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea exertional (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21109** | click or scan EU-EC-10008120146 | | 2021-03-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute cardiac event (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Electrocardiogram ST segment abnormal (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21110** | click or scan EU-EC-10008120002 | | 2021-03-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - ), Muscle twitching (n/a - Unknown - ), Petechiae (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **21111** | click or scan EU-EC-10008119952 | | 2021-03-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **21112** | click or scan EU-EC-10008119754 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | Burning sensation (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **21113** | click or scan EU-EC-10008119672 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular]) |
| **21114** | click or scan EU-EC-10008119512 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Unknown - Other Medically Important Condition), Heart rate increased (2d - Fatal - **Results in Death**), Loss of consciousness (2d - Fatal - **Results in Death**), Pallor (n/a - Unknown - Other Medically Important Condition), Pupil fixed (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory rate increased (2d - Fatal - **Results in Death**), Somnolence (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **21115** | click or scan EU-EC-10008119443 | | 2021-03-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21116** | click or scan EU-EC-10008119333 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (3d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21117 | click or scan EU-EC-10008119281 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Agitation (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Extensor plantar response (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Livedo reticularis (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pallor (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Patient uncooperative (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Peripheral coldness (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 21118 | click or scan EU-EC-10008119261 | | 2021-03-29 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Infection (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Rib fracture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 21119 | click or scan EU-EC-10008118561 | | 2021-03-28 | Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21120 | click or scan EU-EC-10008118074 | | 2021-03-28 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 21121 | click or scan EU-EC-10008117793 | | 2021-03-28 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Asthenia (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Lymph node pain (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 21122 | click or scan EU-EC-10008092499 | | 2021-03-28 | Healthcare Professional | EEA | More than 85 Years | Female | Body temperature decreased (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 21123 | click or scan EU-EC-10008116188 | | 2021-03-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21124 | click or scan EU-EC-10008114818 | | 2021-03-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21125 | click or scan EU-EC-10008114554 | | 2021-03-27 | Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21126 | click or scan EU-EC-10008114486 | | 2021-03-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21127 | click or scan EU-EC-10008114118 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Cough (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Hypotension (n/a - Unknown - **Results in Death**), Lower respiratory tract infection (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Unknown - **Results in Death**), Tachycardia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21128 | click or scan EU-EC-10008113804 | | 2021-03-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21129 | click or scan EU-EC-10008112143 | | 2021-03-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21130 | click or scan EU-EC-10008112138 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Feeling of body temperature change (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia viral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21131 | click or scan EU-EC-10008111295 | | 2021-03-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21132 | click or scan EU-EC-10008111218 | | 2021-03-27 | Healthcare Professional | Non EEA | Not Specified | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 21133 | click or scan EU-EC-10008110874 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Unknown - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21134 | click or scan EU-EC-10008110854 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Illness (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21135 | click or scan EU-EC-10008109297 | | 2021-03-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Sinus tachycardia (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21136 | click or scan EU-EC-10008109272 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diffuse vasculitis (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Purpura (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21137 | click or scan EU-EC-10008109009 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Not Recovered/Not Resolved - **Results in Death**), Acute respiratory distress syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**), Lung infiltration (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocarditis (n/a - Unknown - **Results in Death**), Pneumonitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21138 | click or scan EU-EC-10008108562 | | 2021-03-27 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21139 | click or scan EU-EC-10008108450 | | 2021-03-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21140 | click or scan EU-EC-10008108249 | | 2021-03-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**), Transient ischaemic attack (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21141 | click or scan EU-EC-10008104380 | | 2021-03-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21142 | click or scan EU-EC-10008103207 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21143 | click or scan EU-EC-10008098206 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21144 | click or scan EU-EC-10008096921 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21145 | click or scan EU-EC-10008096858 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (9d - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - n/a]) |
| 21146 | click or scan EU-EC-10008096795 | | 2021-03-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Recovered/Resolved - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21147 | click or scan EU-EC-10008096761 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21148 | click or scan EU-EC-10008096694 | | 2021-03-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 21149 | click or scan EU-EC-10008096650 | | 2021-03-27 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21150 | click or scan EU-EC-10008096608 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Decreased appetite (n/a - Recovered/Resolved - **Results in Death**), Insomnia (n/a - Recovered/Resolved - **Results in Death**), Myocardial rupture (n/a - Not Recovered/Not Resolved - **Results in Death**), Pericardial haemorrhage (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21151 | click or scan EU-EC-10008096606 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Life Threatening), Death (0d - Fatal - **Results in Death**, Life Threatening), Decreased appetite (n/a - Unknown - **Results in Death**, Life Threatening), Lethargy (n/a - Unknown - **Results in Death**, Life Threatening), Tremor (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21152 | click or scan EU-EC-10008096534 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21153 | click or scan EU-EC-10008096531 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (23d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21154 | click or scan EU-EC-10008096526 | | 2021-03-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Ischaemic stroke (19d - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21155 | click or scan EU-EC-10008096500 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21156 | click or scan EU-EC-10008096051 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21157 | click or scan EU-EC-10008095975 | | 2021-03-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Gastrooesophageal reflux disease (n/a - Unknown - **Results in Death**, Life Threatening), Lung neoplasm malignant (n/a - Unknown - **Results in Death**, Life Threatening), Thrombosis (31d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21158 | click or scan EU-EC-10008095728 | | 2021-03-27 | Healthcare Professional | Non EEA | Not Specified | Male | Hospitalisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21159 | click or scan EU-EC-10008095402 | | 2021-03-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21160 | click or scan EU-EC-10008094545 | | 2021-03-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21161 | click or scan EU-EC-10008094491 | | 2021-03-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21162 | click or scan EU-EC-10008094106 | | 2021-03-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21163 | click or scan EU-EC-10008093816 | | 2021-03-27 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (3d - Fatal - **Results in Death**), Presyncope (3d - Fatal - **Results in Death**), Syncope (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [CARBOPLATIN] (S - Bladder neoplasm - Not applicable - [n/a - 300mg - Intravenous (not otherwise specified)]), [GEMCITABINE, GEMCITABINE HYDROCHLORIDE] (S - Bladder neoplasm - Not applicable - [n/a - 1490mg - Intravenous (not otherwise specified)]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21164 | click or scan EU-EC-10008093814 | | 2021-03-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Chills (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21165 | click or scan EU-EC-10008093802 | | 2021-03-27 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21166 | click or scan EU-EC-10008093127 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21167 | click or scan EU-EC-10008092065 | | 2021-03-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 21168 | click or scan EU-EC-10008091696 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21169 | click or scan EU-EC-10008091610 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21170 | click or scan EU-EC-10008091441 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21171 | click or scan EU-EC-10008091287 | | 2021-03-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Illness (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nocturia (n/a - Unknown - ), Pollakiuria (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21172 | click or scan EU-EC-10008091265 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombocytopenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21173 | click or scan EU-EC-10008091233 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21174 | click or scan EU-EC-10008091198 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21175 | click or scan EU-EC-10008090935 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Fatal - **Results in Death**), End stage renal disease (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Life Threatening), Hypertension (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21176 | click or scan EU-EC-10008090852 | | 2021-03-26 | Non Healthcare Professional | EEA | Not Specified | Male | Brain death (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21177 | click or scan EU-EC-10008090748 | | 2021-03-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Diet refusal (21d - Unknown - ), Refusal of treatment by patient (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21178 | click or scan EU-EC-10008090657 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Pyrexia (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 21179 | click or scan EU-EC-10008089870 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - .3mL - Intramuscular]) |
| 21180 | click or scan EU-EC-10008089739 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 21181 | click or scan EU-EC-10008089651 | | 2021-03-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Unknown - ), COVID-19 pneumonia (8d - Unknown - ), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Emotional distress (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rales (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21182 | click or scan EU-EC-10008089010 | | 2021-03-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 21183 | click or scan EU-EC-10008088531 | | 2021-03-26 | Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21184 | click or scan EU-EC-10008087961 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21185 | click or scan EU-EC-10008087296 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21186 | click or scan EU-EC-10008087174 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | Blood pressure decreased (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21187 | click or scan EU-EC-10008087079 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21188 | click or scan EU-EC-10008087054 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (9d - Recovered/Resolved - ), Dyspnoea (9d - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (9d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21189 | click or scan EU-EC-10008087021 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21190 | click or scan EU-EC-10008087019 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21191 | click or scan EU-EC-10008087000 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Haematemesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (S - Hypertension - n/a - [n/a - 5mg - Oral]), [CANDESARTAN CILEXETIL] (S - Hypertension - n/a - [n/a - 16mg - Oral]) |
| 21192 | click or scan EU-EC-10008086990 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Myalgia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21193 | click or scan EU-EC-10008086887 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21194 | click or scan EU-EC-10008086347 | | 2021-03-26 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21195** | click or scan EU-EC-10008085807 |  | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21196** | click or scan EU-EC-10008085486 |  | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| **21197** | click or scan EU-EC-10008085474 |  | 2021-03-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **21198** | click or scan EU-EC-10008085045 |  | 2021-03-26 | Non Healthcare Professional | EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21199** | click or scan EU-EC-10008084957 |  | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21200** | click or scan EU-EC-10008084944 |  | 2021-03-26 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21201** | click or scan EU-EC-10008084896 |  | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **21202** | click or scan EU-EC-10008084555 |  | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Diarrhoea (1d - Unknown - Other Medically Important Condition), Malaise (1d - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]) |
| **21203** | click or scan EU-EC-10008084122 |  | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21204** | click or scan EU-EC-10008084095 |  | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21205** | click or scan EU-EC-10008083648 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21206** | click or scan EU-EC-10008083576 | | 2021-03-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21207** | click or scan EU-EC-10008083484 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **21208** | click or scan EU-EC-10008083376 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21209** | click or scan EU-EC-10008083211 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **21210** | click or scan EU-EC-10008082897 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **21211** | click or scan EU-EC-10008082826 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (3d - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Diarrhoea (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21212** | click or scan EU-EC-10008082756 | | 2021-03-26 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Pulmonary oedema (0d - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21213** | click or scan EU-EC-10008082351 | | 2021-03-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ), Hyperkalaemia (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21214** | click or scan EU-EC-10008082101 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21215 | click or scan EU-EC-10008082093 | | 2021-03-26 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21216 | click or scan EU-EC-10008082092 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21217 | click or scan EU-EC-10008081819 | | 2021-03-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Volvulus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21218 | click or scan EU-EC-10008081791 | | 2021-03-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21219 | click or scan EU-EC-10008081788 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21220 | click or scan EU-EC-10008081671 | | 2021-03-26 | Healthcare Professional | EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Rash pruritic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR]) |
| 21221 | click or scan EU-EC-10008081578 | | 2021-03-26 | Non Healthcare Professional | EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21222 | click or scan EU-EC-10008080901 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Other Medically Important Condition), Back pain (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Embolic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21223 | click or scan EU-EC-10008080885 | | 2021-03-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Inflammation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21224 | click or scan EU-EC-10008080824 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21225 | click or scan EU-EC-10008080814 | | 2021-03-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Unknown - ), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Productive cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rales (4d - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21226 | click or scan EU-EC-10008080064 | | 2021-03-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dry mouth (n/a - Unknown - ), Dyspnoea (1d - Unknown - ), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21227 | click or scan EU-EC-10008078388 | | 2021-03-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21228 | click or scan EU-EC-10008079215 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 21229 | click or scan EU-EC-10008079019 | | 2021-03-25 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21230 | click or scan EU-EC-10008078810 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemothorax (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21231 | click or scan EU-EC-10008078789 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ascites (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - ), Bacteraemia (n/a - Fatal - **Results in Death**), Catheter site haemorrhage (n/a - Fatal - **Results in Death**), Complication associated with device (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Hip fracture (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21232 | click or scan EU-EC-10008078068 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21233 | click or scan EU-EC-10008077752 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Brain herniation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral mass effect (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Encephalitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Meningioma (n/a - Unknown - Caused/Prolonged Hospitalisation), Subdural haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Vasogenic cerebral oedema (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21234 | click or scan EU-EC-10008077565 | | 2021-03-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21235** | click or scan EU-EC-10008077066 | | 2021-03-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (3d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21236** | click or scan EU-EC-10008076808 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21237** | click or scan EU-EC-10008076617 | | 2021-03-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| **21238** | click or scan EU-EC-10008076407 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21239** | click or scan EU-EC-10008076259 | | 2021-03-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Band neutrophil count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blast cell count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Leukaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Metamyelocyte count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Monocyte count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Myelocyte count increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Neutrophil count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Platelet count decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Red cell distribution width increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21240** | click or scan EU-EC-10008075938 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Flatulence (n/a - Unknown - ), Headache (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21241** | click or scan EU-EC-10008074430 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21242** | click or scan EU-EC-10008074420 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **21243** | click or scan EU-EC-10008074317 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Epistaxis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21244** | click or scan EU-EC-10008074225 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21245** | click or scan EU-EC-10008074216 | | 2021-03-25 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Haematoma (n/a - Unknown - ), Road traffic accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **21246** | click or scan EU-EC-10008073930 | | 2021-03-25 | Healthcare Professional | EEA | 18-64 Years | Male | Chills (n/a - Unknown - ), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **21247** | click or scan EU-EC-10008073888 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21248** | click or scan EU-EC-10008073529 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **21249** | click or scan EU-EC-10008073454 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21250** | click or scan EU-EC-10008073446 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21251** | click or scan EU-EC-10008073127 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21252** | click or scan EU-EC-10008073107 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fluid intake reduced (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21253** | click or scan EU-EC-10008072974 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **21254** | click or scan EU-EC-10008072937 | | 2021-03-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21255** | click or scan EU-EC-10008072764 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21256** | click or scan EU-EC-10008072542 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21257** | click or scan EU-EC-10008072487 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21258** | click or scan EU-EC-10008072109 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Unknown - ), Injection site erythema (5d - Recovered/Resolved - ), Injection site inflammation (5d - Recovered/Resolved - ), Injection site warmth (5d - Recovered/Resolved - ), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21259** | click or scan EU-EC-10008071882 | | 2021-03-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21260** | click or scan EU-EC-10008071709 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21261 | click or scan EU-EC-10008071698 | | 2021-03-25 | Non Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21262 | click or scan EU-EC-10008071631 | | 2021-03-25 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21263 | click or scan EU-EC-10008071293 | | 2021-03-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (3d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21264 | click or scan EU-EC-10008070645 | | 2021-03-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (1d - Fatal - **Results in Death**), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21265 | click or scan EU-EC-10008070169 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21266 | click or scan EU-EC-10008069790 | | 2021-03-25 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Headache (n/a - Unknown - ), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21267 | click or scan EU-EC-10008069253 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 21268 | click or scan EU-EC-10008068893 | | 2021-03-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Clot retraction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Constipation (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21269 | click or scan EU-EC-10008068236 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21270 | click or scan EU-EC-10008068036 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (15d - Fatal - **Results in Death**), Peripheral ischaemia (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21271 | click or scan EU-EC-10008067956 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Male | Left ventricular dysfunction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21272 | click or scan EU-EC-10008067916 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Brain hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Herpes simplex encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21273 | click or scan EU-EC-10008067884 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Rectal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21274 | click or scan EU-EC-10008067878 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Rectal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21275 | click or scan EU-EC-10008067677 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (S - Parkinsonism - Dose increased - [n/a - n/a - Oral]), [GALANTAMINE HYDROBROMIDE] (S - Dementia Alzheimer's type - Dose not changed - [n/a - n/a - Oral]) |
| 21276 | click or scan EU-EC-10008067560 | | 2021-03-25 | Healthcare Professional | EEA | 18-64 Years | Male | Carotid artery dissection (n/a - Fatal - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21277 | click or scan EU-EC-10008066454 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Bed rest (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Restlessness (n/a - Unknown - ), Urge incontinence (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 21278 | click or scan EU-EC-10008066318 | | 2021-03-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21279 | click or scan EU-EC-10008066296 | | 2021-03-25 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 21280 | click or scan EU-EC-10008066112 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Male | Aphasia (8d - Fatal - **Results in Death**), Cerebral infarction (8d - Fatal - **Results in Death**), Hemiparesis (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21281 | click or scan EU-EC-10008065722 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Dehydration (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21282 | click or scan EU-EC-10008065504 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Female | Coma (3d - Fatal - **Results in Death**), Hypotonia (3d - Fatal - **Results in Death**), Sudden death (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 21283 | click or scan EU-EC-10008065355 | | 2021-03-25 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 21284 | click or scan EU-EC-10008065204 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Illness (32d - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21285 | click or scan EU-EC-10008065025 | | 2021-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21286 | click or scan EU-EC-10008064686 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21287 | click or scan EU-EC-10008064654 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21288 | click or scan EU-EC-10008064575 | | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21289 | click or scan EU-EC-10008064473 | | 2021-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Incoherent (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21290 | click or scan EU-EC-10008064337 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21291 | click or scan EU-EC-10008064304 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21292 | click or scan EU-EC-10008064079 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Choking (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2d - n/a - Intramuscular]) |
| 21293 | click or scan EU-EC-10008064071 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 21294 | click or scan EU-EC-10008063412 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Back pain (n/a - Unknown - ), Cardiac ventricular thrombosis (n/a - Fatal - **Results in Death**), Dyspnoea (0d - Recovered/Resolved - ), Dyspnoea (1d - Recovering/Resolving - ), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Scrotal injury (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21295 | click or scan EU-EC-10008063213 | | 2021-03-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Not Recovered/Not Resolved - ), Hypotonia (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21296 | click or scan EU-EC-10008063209 | | 2021-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Hypotonia (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21297 | click or scan EU-EC-10008063204 | | 2021-03-24 | Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Prophylaxis - n/a - [n/a - n/a - Unknown]) |
| 21298 | click or scan EU-EC-10008062957 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21299 | click or scan EU-EC-10008062451 | | 2021-03-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| 21300 | click or scan EU-EC-10008062208 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Life Threatening), Acute respiratory distress syndrome (4d - Fatal - **Results in Death**), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Life Threatening), Cytokine release syndrome (n/a - Unknown - Life Threatening), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyponatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung opacity (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21301 | click or scan EU-EC-10008061909 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blister (1d - Fatal - **Results in Death**), Chills (1d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21302 | click or scan EU-EC-10008061818 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal tenderness (n/a - Unknown - ), Apnoeic attack (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Dehydration (n/a - Unknown - ), Hypophagia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21303 | click or scan EU-EC-10008061596 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21304 | click or scan EU-EC-10008061249 | | 2021-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21305 | click or scan EU-EC-10008061128 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Influenza like illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21306 | click or scan EU-EC-10008061070 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21307 | click or scan EU-EC-10008061004 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21308 | click or scan EU-EC-10008060929 | | 2021-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blood glucose increased (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21309 | click or scan EU-EC-10008060858 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21310 | click or scan EU-EC-10008060841 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21311 | click or scan EU-EC-10008060325 | | 2021-03-24 | Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gait disturbance (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21312 | click or scan EU-EC-10008060200 | | 2021-03-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Breath sounds abnormal (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Vomiting (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21313 | click or scan EU-EC-10008060163 | | 2021-03-24 | Healthcare Professional | Non EEA | Not Specified | Female | Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21314 | click or scan EU-EC-10008059980 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bedridden (n/a - Not Recovered/Not Resolved - ), Death (1d - Fatal - **Results in Death**), Dysphagia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21315 | click or scan EU-EC-10008059850 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21316 | click or scan EU-EC-10008059698 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 21317 | click or scan EU-EC-10008059610 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypercalcaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21318 | click or scan EU-EC-10008059465 | | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1h - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21319 | click or scan EU-EC-10008059379 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 21320 | click or scan EU-EC-10008059264 | | 2021-03-24 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21321 | click or scan EU-EC-10008059187 |  | 2021-03-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Life Threatening), Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Life Threatening), Dizziness (n/a - Unknown - ), Hypotension (n/a - Unknown - Life Threatening), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21322 | click or scan EU-EC-10008058681 |  | 2021-03-24 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 21323 | click or scan EU-EC-10008058631 |  | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21324 | click or scan EU-EC-10008058536 |  | 2021-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21325 | click or scan EU-EC-10008057309 |  | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21326 | click or scan EU-EC-10008057293 |  | 2021-03-24 | Healthcare Professional | EEA | 18-64 Years | Female | Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricle rupture (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21327 | click or scan EU-EC-10008057237 |  | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21328 | click or scan EU-EC-10008057220 |  | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Female | Lymphocytic infiltration (n/a - Fatal - **Results in Death**), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**), Pulmonary vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21329 | click or scan EU-EC-10008056568 |  | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21330 | click or scan EU-EC-10008056333 |  | 2021-03-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Pulmonary hypertension (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21331 | click or scan EU-EC-10008056331 |  | 2021-03-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21332 | click or scan EU-EC-10008056287 | | 2021-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21333 | click or scan EU-EC-10008056263 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21334 | click or scan EU-EC-10008055634 | | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21335 | click or scan EU-EC-10008055539 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal infection (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21336 | click or scan EU-EC-10008055288 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tremor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21337 | click or scan EU-EC-10008055181 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21338 | click or scan EU-EC-10008054936 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Erysipelas (n/a - Recovered/Resolved - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Rhabdomyolysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21339 | click or scan EU-EC-10008054923 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Lung disorder (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21340 | click or scan EU-EC-10008054921 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Diabetic hyperosmolar coma (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21341 | click or scan EU-EC-10008054752 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21342** | click or scan EU-EC-10008054510 | | 2021-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21343** | click or scan EU-EC-10008054507 | | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21344** | click or scan EU-EC-10008054177 | | 2021-03-24 | Healthcare Professional | EEA | 18-64 Years | Female | Headache (n/a - Unknown - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), [DICLOFENAC DIETHYLAMINE, DICLOFENAC SODIUM] (S - Arthralgia - n/a - [n/a - n/a - Cutaneous]), [NAPROXEN SODIUM, NAPROXEN SODIUM ANHYDROUS] (S - Arthralgia - n/a - [n/a - 550mg - Oral]) |
| **21345** | click or scan EU-EC-10008054068 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21346** | click or scan EU-EC-10008054052 | | 2021-03-24 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21347** | click or scan EU-EC-10008054030 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Bradycardia (n/a - Not Recovered/Not Resolved - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21348** | click or scan EU-EC-10008054008 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Recovered/Resolved - **Results in Death**), Malaise (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21349** | click or scan EU-EC-10008053996 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21350** | click or scan EU-EC-10008053919 | | 2021-03-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anaemia (n/a - Not Recovered/Not Resolved - **Results in Death**), Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Atrial fibrillation (n/a - Unknown - **Results in Death**), Atrioventricular block (n/a - Not Recovered/Not Resolved - **Results in Death**), Bradycardia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiac arrest (n/a - Recovered/Resolved With Sequelae - **Results in Death**), Diplopia (n/a - Not Recovered/Not Resolved - **Results in Death**), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypothermia (n/a - Not Recovered/Not Resolved - **Results in Death**), Myalgia (n/a - Unknown - **Results in Death**), Nervous system disorder (n/a - Fatal - **Results in Death**), Parkinsonism (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Thrombocytopenia (19d - Recovered/Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21351** | click or scan EU-EC-10008053848 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21352 | click or scan EU-EC-10008053693 | | 2021-03-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21353 | click or scan EU-EC-10008053545 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Hypertensive heart disease (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21354 | click or scan EU-EC-10008053235 | | 2021-03-24 | Non Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21355 | click or scan EU-EC-10008052996 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21356 | click or scan EU-EC-10008052995 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21357 | click or scan EU-EC-10008052992 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21358 | click or scan EU-EC-10008052991 | | 2021-03-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21359 | click or scan EU-EC-10008052990 | | 2021-03-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21360 | click or scan EU-EC-10008052986 | | 2021-03-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21361 | click or scan EU-EC-10008052698 | | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory arrest (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21362** | click or scan EU-EC-10008052521 |  | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21363** | click or scan EU-EC-10008052477 |  | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (3d - Fatal - **Results in Death**), Vaccination failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21364** | click or scan EU-EC-10008052296 |  | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Circulatory collapse (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **21365** | click or scan EU-EC-10008052181 |  | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21366** | click or scan EU-EC-10008052078 |  | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Myalgia (5d - Fatal - **Results in Death**), Regurgitation (5d - Fatal - **Results in Death**), Somnolence (5d - Fatal - **Results in Death**), Vomiting (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **21367** | click or scan EU-EC-10008049903 |  | 2021-03-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (5d - Fatal - **Results in Death**), Facial paralysis (5d - Fatal - **Results in Death**), Monoplegia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21368** | click or scan EU-EC-10008051744 |  | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (1d - Fatal - **Results in Death**), Rash macular (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21369** | click or scan EU-EC-10008051742 |  | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21370** | click or scan EU-EC-10008051730 |  | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21371** | click or scan EU-EC-10008051724 |  | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21372 | click or scan EU-EC-10008051690 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 21373 | click or scan EU-EC-10008051215 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21374 | click or scan EU-EC-10008051201 | | 2021-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Metabolic acidosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21375 | click or scan EU-EC-10008051155 | | 2021-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic stroke (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21376 | click or scan EU-EC-10008051121 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21377 | click or scan EU-EC-10008051094 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21378 | click or scan EU-EC-10008051030 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemolytic anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation), Jaundice (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Shock haemorrhagic (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21379 | click or scan EU-EC-10008050890 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown - More in ICSR]) |
| 21380 | click or scan EU-EC-10008050808 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown - More in ICSR]) |
| 21381 | click or scan EU-EC-10008050747 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Breast haematoma (2d - Fatal - **Results in Death**), Melaena (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [ACENOCOUMAROL] (S - Atrial fibrillation - Drug withdrawn - [101d - n/a - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21382 | click or scan EU-EC-10008050249 | | 2021-03-23 | Healthcare Professional | EEA | Not Specified | Male | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21383 | click or scan EU-EC-10008049763 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21384 | click or scan EU-EC-10008049630 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21385 | click or scan EU-EC-10008049623 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21386 | click or scan EU-EC-10008049615 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21387 | click or scan EU-EC-10008049540 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21388 | click or scan EU-EC-10008049295 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21389 | click or scan EU-EC-10008049164 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hypotension (2d - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (2d - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Small intestinal obstruction (2d - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21390 | click or scan EU-EC-10008048448 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21391 | click or scan EU-EC-10008048302 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21392 | click or scan EU-EC-10008048250 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiovascular disorder (n/a - Unknown - Life Threatening), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Sedation (n/a - Unknown - ), Thrombosis (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21393 | click or scan EU-EC-10008048057 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21394 | click or scan EU-EC-10008048005 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diet refusal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mutism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sedation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21395 | click or scan EU-EC-10008047941 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21396 | click or scan EU-EC-10008047841 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21397 | click or scan EU-EC-10008047801 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anxiety (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Muscular weakness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Nervousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21398 | click or scan EU-EC-10008047490 | | 2021-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21399 | click or scan EU-EC-10008047326 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21400 | click or scan EU-EC-10008047172 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dementia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21401 | click or scan EU-EC-10008047125 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21402 | click or scan EU-EC-10008046788 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21403 | click or scan EU-EC-10008046756 |  | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21404 | click or scan EU-EC-10008046586 |  | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21405 | click or scan EU-EC-10008046562 |  | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21406 | click or scan EU-EC-10008046526 |  | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21407 | click or scan EU-EC-10008046516 |  | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Application site haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Motor dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21408 | click or scan EU-EC-10008046515 |  | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Mouth haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21409 | click or scan EU-EC-10008046514 |  | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21410 | click or scan EU-EC-10008046173 |  | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Small intestinal obstruction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21411 | click or scan EU-EC-10008046126 |  | 2021-03-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Cystitis (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21412 | click or scan EU-EC-10008045848 |  | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21413 | click or scan EU-EC-10008045780 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21414 | click or scan EU-EC-10008045145 | | 2021-03-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21415 | click or scan EU-EC-10008044965 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21416 | click or scan EU-EC-10008044813 | | 2021-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Ventricular tachycardia (n/a - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21417 | click or scan EU-EC-10008044811 | | 2021-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21418 | click or scan EU-EC-10008044792 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Increased upper airway secretion (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory depression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 21419 | click or scan EU-EC-10008044775 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21420 | click or scan EU-EC-10008044609 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening), Respiratory tract infection (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21421 | click or scan EU-EC-10008044504 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21422 | click or scan EU-EC-10008044422 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21423 | click or scan EU-EC-10008044052 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21424 | click or scan EU-EC-10008043889 |  | 2021-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21425 | click or scan EU-EC-10008043745 |  | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21426 | click or scan EU-EC-10008043551 |  | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21427 | click or scan EU-EC-10008043471 |  | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Faecal vomiting (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21428 | click or scan EU-EC-10008043370 |  | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21429 | click or scan EU-EC-10008043340 |  | 2021-03-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21430 | click or scan EU-EC-10008043336 |  | 2021-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21431 | click or scan EU-EC-10008043213 |  | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21432 | click or scan EU-EC-10008043201 |  | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**), Choking (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21433 | click or scan EU-EC-10008043066 |  | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21434 | click or scan EU-EC-10008042916 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21435 | click or scan EU-EC-10008042912 | | 2021-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Haemoperitoneum (n/a - Fatal - **Results in Death**), Splenic rupture (n/a - Fatal - **Results in Death**), Venous thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21436 | click or scan EU-EC-10008042896 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (1d - Unknown - **Results in Death**, Life Threatening), Sudden death (1d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21437 | click or scan EU-EC-10008042722 | | 2021-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), ENTRESTO 49 MG/51 MG FILM-COATED TABLETS [VALSARTAN, SACUBITRIL] (S - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (S - n/a - n/a - [n/a - n/a - Oral]) |
| 21438 | click or scan EU-EC-10008042643 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Decreased appetite (10d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), General physical health deterioration (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21439 | click or scan EU-EC-10008042619 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21440 | click or scan EU-EC-10008042141 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21441 | click or scan EU-EC-10008042099 | | 2021-03-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (4d - Fatal - **Results in Death**, Life Threatening), Fatigue (4d - Fatal - **Results in Death**, Life Threatening), Irregular sleep wake rhythm disorder (4d - Fatal - **Results in Death**, Life Threatening), Sleep apnoea syndrome (4d - Fatal - **Results in Death**, Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 21442 | click or scan EU-EC-10008042086 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diabetic metabolic decompensation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Feeding disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperglycaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoglycaemic coma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21443 | click or scan EU-EC-10008041909 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21444 | click or scan EU-EC-10008041893 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21445 | click or scan EU-EC-10008041773 | | 2021-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21446 | click or scan EU-EC-10008041738 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Hypophagia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21447 | click or scan EU-EC-10008041695 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Chills (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypokalaemia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Cardiac failure - Drug withdrawn - [n/a - .5mg - n/a]) |
| 21448 | click or scan EU-EC-10008041657 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hand deformity (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**), Livedo reticularis (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21449 | click or scan EU-EC-10008041538 | | 2021-03-23 | Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21450 | click or scan EU-EC-10008041322 | | 2021-03-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Ear pain (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21451 | click or scan EU-EC-10008041320 | | 2021-03-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21452 | click or scan EU-EC-10008041174 | | 2021-03-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Limb discomfort (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21453 | click or scan EU-EC-10008039424 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21454 | click or scan EU-EC-10008039206 | | 2021-03-23 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21455 | click or scan EU-EC-10008039137 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**), Drug ineffective (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Irritability (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21456 | click or scan EU-EC-10008038906 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21457 | click or scan EU-EC-10008038729 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21458 | click or scan EU-EC-10008038430 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Male | Aphthous ulcer (n/a - Fatal - **Results in Death**), General physical condition abnormal (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21459 | click or scan EU-EC-10008038388 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21460 | click or scan EU-EC-10008038347 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21461 | click or scan EU-EC-10008038323 | | 2021-03-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspepsia (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21462 | click or scan EU-EC-10008038025 | | 2021-03-23 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21463 | click or scan EU-EC-10008037076 | | 2021-03-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21464 | click or scan EU-EC-10008037072 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21465 | click or scan EU-EC-10008037062 | | 2021-03-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21466 | click or scan EU-EC-10008036471 | | 2021-03-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (22d - Fatal - **Results in Death**), Cerebrovascular accident (22d - Fatal - **Results in Death**), Paralysis (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21467 | click or scan EU-EC-10008034911 | | 2021-03-23 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21468 | click or scan EU-EC-10008034147 | | 2021-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Feeling abnormal (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21469 | click or scan EU-EC-10008033873 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Combined immunodeficiency (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1mL - Intramuscular]) |
| 21470 | click or scan EU-EC-10008033583 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21471 | click or scan EU-EC-10008033566 | | 2021-03-22 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21472 | click or scan EU-EC-10008033503 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21473 | click or scan EU-EC-10008033444 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening), Fall (1d - Unknown - Life Threatening), Pulseless electrical activity (1d - Unknown - Life Threatening), Unresponsive to stimuli (1d - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21474 | click or scan EU-EC-10008033414 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21475 | click or scan EU-EC-10008033314 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21476 | click or scan EU-EC-10008033157 | | 2021-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21477 | click or scan EU-EC-10008033156 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21478 | click or scan EU-EC-10008033136 | | 2021-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aspiration (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21479 | click or scan EU-EC-10008033069 | | 2021-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Feeling hot (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21480 | click or scan EU-EC-10008032766 | | 2021-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Erythema (n/a - Unknown - ), Haemangioma of skin (n/a - Unknown - ), Purulent discharge (n/a - Unknown - ), Rash (n/a - Unknown - ), Rash macular (n/a - Unknown - ), Scab (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21481 | click or scan EU-EC-10008032600 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21482 | click or scan EU-EC-10008032499 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Urinary tract infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21483 | click or scan EU-EC-10008031636 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (0d - Fatal - **Results in Death**), Hypotension (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21484 | click or scan EU-EC-10008031460 | | 2021-03-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (n/a - Unknown - ), Cardiac failure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21485** | click or scan EU-EC-10008031312 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21486** | click or scan EU-EC-10008031076 | | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - .3mL - Intramuscular]) |
| **21487** | click or scan EU-EC-10008031033 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a]) |
| **21488** | click or scan EU-EC-10008030837 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Malnutrition (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **21489** | click or scan EU-EC-10008030331 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21490** | click or scan EU-EC-10008029860 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21491** | click or scan EU-EC-10008029719 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21492** | click or scan EU-EC-10008029688 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Unknown - ), Fall (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Mesenteric artery embolism (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **21493** | click or scan EU-EC-10008029657 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21494** | click or scan EU-EC-10008029438 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [ACENOCOUMAROL] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21495 | click or scan EU-EC-10008029365 | | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Hyperhidrosis (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21496 | click or scan EU-EC-10008029310 | | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21497 | click or scan EU-EC-10008029303 | | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Diabetes mellitus inadequate control (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21498 | click or scan EU-EC-10008029299 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21499 | click or scan EU-EC-10008029222 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21500 | click or scan EU-EC-10008029214 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21501 | click or scan EU-EC-10008029033 | | 2021-03-22 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21502 | click or scan EU-EC-10008028874 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Resuscitation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21503 | click or scan EU-EC-10008028727 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Infection (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21504 | click or scan EU-EC-10008028670 | | 2021-03-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachypnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21505 | click or scan EU-EC-10008028658 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Auscultation (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21506 | click or scan EU-EC-10008028593 |  | 2021-03-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21507 | click or scan EU-EC-10008028549 |  | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Hypersensitivity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21508 | click or scan EU-EC-10008027130 |  | 2021-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21509 | click or scan EU-EC-10008027106 |  | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain upper (6d - Fatal - **Results in Death**), Diarrhoea (2d - Fatal - **Results in Death**), General physical health deterioration (9d - Fatal - **Results in Death**), Nausea (6d - Fatal - **Results in Death**), Urinary retention (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21510 | click or scan EU-EC-10008027105 |  | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21511 | click or scan EU-EC-10008027099 |  | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21512 | click or scan EU-EC-10008027098 |  | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21513 | click or scan EU-EC-10008027097 |  | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21514 | click or scan EU-EC-10008026955 |  | 2021-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21515 | click or scan EU-EC-10008026910 |  | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**), Incontinence (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21516 | click or scan EU-EC-10008026907 |  | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | Delirium (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21517 | click or scan EU-EC-10008026901 | | 2021-03-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21518 | click or scan EU-EC-10008026782 | | 2021-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Hyperpyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21519 | click or scan EU-EC-10008026654 | | 2021-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21520 | click or scan EU-EC-10008026646 | | 2021-03-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Lymphopenia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21521 | click or scan EU-EC-10008026071 | | 2021-03-22 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21522 | click or scan EU-EC-10008026026 | | 2021-03-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21523 | click or scan EU-EC-10008025458 | | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [21d - .3mL - Intramuscular]) |
| 21524 | click or scan EU-EC-10008025355 | | 2021-03-22 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain lower (n/a - Fatal - **Results in Death**), Anuria (n/a - Fatal - **Results in Death**), Cervical spinal stenosis (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Erythema multiforme (n/a - Fatal - **Results in Death**), Hypotonia (n/a - Fatal - **Results in Death**), Intervertebral disc protrusion (n/a - Fatal - **Results in Death**), Metabolic acidosis (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**), Paraparesis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Swelling (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 21525 | click or scan EU-EC-10008025278 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21526 | click or scan EU-EC-10008024945 | | 2021-03-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21527 | click or scan EU-EC-10008023598 |  | 2021-03-22 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21528 | click or scan EU-EC-10008023532 |  | 2021-03-22 | Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21529 | click or scan EU-EC-10008022829 |  | 2021-03-21 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21530 | click or scan EU-EC-10008021578 |  | 2021-03-21 | Non Healthcare Professional | EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21531 | click or scan EU-EC-10008020026 |  | 2021-03-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 21532 | click or scan EU-EC-10008018522 |  | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21533 | click or scan EU-EC-10008018107 |  | 2021-03-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cognitive disorder (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21534 | click or scan EU-EC-10008017838 |  | 2021-03-20 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21535 | click or scan EU-EC-10008017826 |  | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Agitation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Photophobia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pollakiuria (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 21536 | click or scan EU-EC-10008017769 |  | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (5h - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21537 | click or scan EU-EC-10008017765 | | 2021-03-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - **Results in Death**), Lethargy (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21538 | click or scan EU-EC-10008017501 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (2d - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21539 | click or scan EU-EC-10008017500 | | 2021-03-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21540 | click or scan EU-EC-10008017325 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21541 | click or scan EU-EC-10008016635 | | 2021-03-20 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21542 | click or scan EU-EC-10008016623 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (3d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21543 | click or scan EU-EC-10008016322 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Unknown - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21544 | click or scan EU-EC-10008015734 | | 2021-03-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21545 | click or scan EU-EC-10008015656 | | 2021-03-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (15d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 21546 | click or scan EU-EC-10008015600 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Unknown - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Pulse absent (n/a - Unknown - **Results in Death**), Seizure (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21547 | click or scan EU-EC-10008015387 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21548 | click or scan EU-EC-10008014638 | | 2021-03-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21549 | click or scan EU-EC-10008014441 | | 2021-03-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21550 | click or scan EU-EC-10008014323 | | 2021-03-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Aneurysm (n/a - Fatal - **Results in Death**), Retinal exudates (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21551 | click or scan EU-EC-10008014020 | | 2021-03-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Panic attack (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21552 | click or scan EU-EC-10008013780 | | 2021-03-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Depression (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21553 | click or scan EU-EC-10008013618 | | 2021-03-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Oxygen saturation decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| 21554 | click or scan EU-EC-10008013600 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21555 | click or scan EU-EC-10008013596 | | 2021-03-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 pneumonia (4d - Fatal - **Results in Death**, Life Threatening), Myalgia (n/a - Unknown - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21556 | click or scan EU-EC-10008013584 | | 2021-03-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypertensive heart disease (1d - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21557** | click or scan EU-EC-10008013329 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **21558** | click or scan EU-EC-10008013276 | | 2021-03-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (5d - Fatal - **Results in Death**), Myocardial infarction (5d - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (5d - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21559** | click or scan EU-EC-10008013203 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Cerebral ischaemia (n/a - Unknown - **Results in Death**, Life Threatening), Ventricular fibrillation (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **21560** | click or scan EU-EC-10008012388 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **21561** | click or scan EU-EC-10008012060 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **21562** | click or scan EU-EC-10008012016 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Hyperhidrosis (n/a - Unknown - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **21563** | click or scan EU-EC-10008011752 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **21564** | click or scan EU-EC-10008011643 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Coronary artery thrombosis (1d - Not Recovered/Not Resolved - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (2d - Recovered/Resolved - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**), Pain in extremity (2d - Recovered/Resolved - **Results in Death**), Vaccination site pain (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **21565** | click or scan EU-EC-10008011308 | | 2021-03-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21566 | click or scan EU-EC-10008011298 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dysgeusia (n/a - Not Recovered/Not Resolved - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21567 | click or scan EU-EC-10008011289 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Cerebrovascular accident (8d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Parenteral]) |
| 21568 | click or scan EU-EC-10008011189 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (4d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21569 | click or scan EU-EC-10008010888 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21570 | click or scan EU-EC-10008010695 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21571 | click or scan EU-EC-10008009992 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21572 | click or scan EU-EC-10008009380 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21573 | click or scan EU-EC-10008008357 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21574 | click or scan EU-EC-10008008063 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - **Results in Death**), Paraesthesia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21575 | click or scan EU-EC-10008007840 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21576 | click or scan EU-EC-10008007819 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21577 | click or scan EU-EC-10008007266 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21578 | click or scan EU-EC-10008007030 | | 2021-03-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Venous thrombosis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21579 | click or scan EU-EC-10008006377 | | 2021-03-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - **Results in Death**, Life Threatening), Haemorrhage intracranial (n/a - Unknown - **Results in Death**, Life Threatening), Headache (n/a - Unknown - **Results in Death**, Life Threatening), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21580 | click or scan EU-EC-10008006339 | | 2021-03-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**), Circulatory collapse (n/a - Unknown - **Results in Death**), Food refusal (n/a - Unknown - **Results in Death**), Hypoglycaemia (n/a - Unknown - **Results in Death**), Ischaemic stroke (n/a - Unknown - **Results in Death**), Listless (n/a - Unknown - **Results in Death**), Metabolic syndrome (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Peripheral circulatory failure (n/a - Unknown - **Results in Death**), Skin discolouration (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21581 | click or scan EU-EC-10008006266 | | 2021-03-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Lethargy (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 21582 | click or scan EU-EC-10008006225 | | 2021-03-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (14d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21583 | click or scan EU-EC-10008006179 | | 2021-03-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21584 | click or scan EU-EC-10008005972 | | 2021-03-20 | Healthcare Professional | EEA | 65-85 Years | Male | Adverse event following immunisation (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21585 | click or scan EU-EC-10008005950 | | 2021-03-20 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21586 | click or scan EU-EC-10008005329 |  | 2021-03-20 | Healthcare Professional | EEA | More than 85 Years | Female | Gastrointestinal haemorrhage (4d - Fatal - **Results in Death**), Haematemesis (4d - Fatal - **Results in Death**), Haemoperitoneum (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), LIXIANA 30 MG FILM-COATED TABLETS [EDOXABAN] (S - Atrial fibrillation - Drug withdrawn - [n/a - 1 {DF} - Oral]) |
| 21587 | click or scan EU-EC-10008005098 |  | 2021-03-20 | Healthcare Professional | EEA | More than 85 Years | Female | Body temperature increased (8d - Fatal - **Results in Death**), SARS-CoV-2 test (8d - Fatal - **Results in Death**), Vaccination complication (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21588 | click or scan EU-EC-10008004178 |  | 2021-03-20 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21589 | click or scan EU-EC-10008002509 |  | 2021-03-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Hepatic failure (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - Life Threatening), Renal failure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21590 | click or scan EU-EC-10008002389 |  | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21591 | click or scan EU-EC-10008002370 |  | 2021-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cyanosis (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21592 | click or scan EU-EC-10008002294 |  | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21593 | click or scan EU-EC-10008002290 |  | 2021-03-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21594 | click or scan EU-EC-10008002240 |  | 2021-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21595 | click or scan EU-EC-10008001906 |  | 2021-03-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Illness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21596 | click or scan EU-EC-10008001873 | | 2021-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21597 | click or scan EU-EC-10008001828 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21598 | click or scan EU-EC-10008001680 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hepatorenal syndrome (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21599 | click or scan EU-EC-10008001624 | | 2021-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21600 | click or scan EU-EC-10008001487 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21601 | click or scan EU-EC-10008001426 | | 2021-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21602 | click or scan EU-EC-10008001401 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21603 | click or scan EU-EC-10008001196 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21604 | click or scan EU-EC-10008001158 | | 2021-03-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Unknown - **Results in Death**), Seizure (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21605 | click or scan EU-EC-10008001106 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21606 | click or scan EU-EC-10008000949 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradykinesia (1d - Unknown - ), Fall (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21607 | click or scan EU-EC-10008000784 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastroenteritis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 21608 | click or scan EU-EC-10008000584 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21609 | click or scan EU-EC-10008000575 | | 2021-03-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21610 | click or scan EU-EC-10007999647 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21611 | click or scan EU-EC-10007999464 | | 2021-03-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysstasia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin discolouration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 21612 | click or scan EU-EC-10007999377 | | 2021-03-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pain in extremity (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21613 | click or scan EU-EC-10007999342 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (1d - Recovered/Resolved - ), Respiratory distress (6d - Fatal - **Results in Death**), Use of accessory respiratory muscles (1d - Recovered/Resolved - ), Wheezing (1d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21614 | click or scan EU-EC-10007998926 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21615 | click or scan EU-EC-10007998689 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Female | Encephalitis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21616 | click or scan EU-EC-10007998037 | | 2021-03-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21617 | click or scan EU-EC-10007997867 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphasia (n/a - Unknown - ), Communication disorder (n/a - Unknown - ), Contusion (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21618 | click or scan EU-EC-10007997689 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21619 | click or scan EU-EC-10007997672 | | 2021-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Blood cholesterol increased (n/a - Unknown - ), Blood glucose increased (n/a - Unknown - ), Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21620 | click or scan EU-EC-10007997449 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21621 | click or scan EU-EC-10007997271 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - ), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Hallucination - Dose reduced - [n/a - 2 {DF} - n/a]) |
| 21622 | click or scan EU-EC-10007997157 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory failure (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21623 | click or scan EU-EC-10007997083 | | 2021-03-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 21624 | click or scan EU-EC-10007997040 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Subcutaneous]) |
| 21625 | click or scan EU-EC-10007996739 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21626 | click or scan EU-EC-10007996721 | | 2021-03-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21627 | click or scan EU-EC-10007996512 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**), Fibromyalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 21628 | click or scan EU-EC-10007996490 | | 2021-03-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral artery embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21629 | click or scan EU-EC-10007996473 | | 2021-03-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21630 | click or scan EU-EC-10007996439 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21631 | click or scan EU-EC-10007996183 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| 21632 | click or scan EU-EC-10007996182 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination complication (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21633 | click or scan EU-EC-10007995724 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21634 | click or scan EU-EC-10007994792 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial flutter (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21635 | click or scan EU-EC-10007994787 | | 2021-03-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Oedema (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21636 | click or scan EU-EC-10007994783 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Haemorrhage intracranial (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Disabling), Hypothermia (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21637 | click or scan EU-EC-10007994140 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Eating disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Toxicity to various agents (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21638 | click or scan EU-EC-10007993690 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 21639 | click or scan EU-EC-10007993481 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Female | Craniocerebral injury (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fall (0d - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Subarachnoid haemorrhage (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subdural haemorrhage (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Syncope (0d - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21640 | click or scan EU-EC-10007993477 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure congestive (5d - Fatal - **Results in Death**), Metabolic disorder (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21641 | click or scan EU-EC-10007993251 | | 2021-03-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 21642 | click or scan EU-EC-10007993065 | | 2021-03-19 | Healthcare Professional | EEA | Not Specified | Male | Vaccination complication (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21643 | click or scan EU-EC-10007992903 | | 2021-03-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cold sweat (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21644 | click or scan EU-EC-10007992532 | | 2021-03-19 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21645 | click or scan EU-EC-10007992341 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Male | General physical condition abnormal (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21646 | click or scan EU-EC-10007992226 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (13d - Fatal - **Results in Death**), Pneumonia (13d - Fatal - **Results in Death**), Sepsis (13d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21647 | click or scan EU-EC-10007992106 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21648 | click or scan EU-EC-10007992075 | | 2021-03-19 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic aneurysm (n/a - Fatal - **Results in Death**), Aortic dissection (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Haemothorax (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21649 | click or scan EU-EC-10007991846 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Hypernatraemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21650 | click or scan EU-EC-10007991591 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Mydriasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21651 | click or scan EU-EC-10007991552 | | 2021-03-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypertension (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21652 | click or scan EU-EC-10007991013 | | 2021-03-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21653 | click or scan EU-EC-10007990853 | | 2021-03-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21654 | click or scan EU-EC-10007990665 | | 2021-03-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21655 | click or scan EU-EC-10007990651 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21656 | click or scan EU-EC-10007990505 | | 2021-03-19 | Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21657 | click or scan EU-EC-10007990419 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21658 | click or scan EU-EC-10007990396 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]), [CLOZAPINE] (S - Schizophrenia - Dose not changed - [n/a - 100mg - Oral]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (S - Schizophrenia - Dose not changed - [n/a - 20[drp] - Oral]), [MIDODRINE HYDROCHLORIDE] (S - Orthostatic hypotension - Dose not changed - [n/a - 2.5mg - Oral]) |
| 21659 | click or scan EU-EC-10007990233 | | 2021-03-19 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21660 | click or scan EU-EC-10007989838 | | 2021-03-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Intestinal infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21661 | click or scan EU-EC-10007988382 | | 2021-03-19 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Cardiopulmonary failure (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 21662 | click or scan EU-EC-10007985304 | | 2021-03-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Aneurysm (n/a - Fatal - **Results in Death**), Erythema (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21663 | click or scan EU-EC-10007985206 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21664 | click or scan EU-EC-10007985048 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |
| 21665 | click or scan EU-EC-10007985030 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Severe acute respiratory syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21666 | click or scan EU-EC-10007985009 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Respiration abnormal (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21667 | click or scan EU-EC-10007984461 | | 2021-03-18 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21668 | click or scan EU-EC-10007984348 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21669 | click or scan EU-EC-10007983908 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21670 | click or scan EU-EC-10007983731 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21671 | click or scan EU-EC-10007983355 | | 2021-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21672 | click or scan EU-EC-10007982751 | | 2021-03-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Anuria (n/a - Unknown - Other Medically Important Condition), Balance disorder (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Urinary retention (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21673 | click or scan EU-EC-10007982603 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a - More in ICSR]) |
| 21674 | click or scan EU-EC-10007982602 | | 2021-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| 21675 | click or scan EU-EC-10007982584 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21676 | click or scan EU-EC-10007981982 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21677 | click or scan EU-EC-10007981895 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21678 | click or scan EU-EC-10007980725 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a]) |
| 21679 | click or scan EU-EC-10007980285 | | 2021-03-18 | Healthcare Professional | EEA | Not Specified | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21680 | click or scan EU-EC-10007980135 | | 2021-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21681 | click or scan EU-EC-10007979942 | | 2021-03-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Recovering/Resolving - ), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21682 | click or scan EU-EC-10007979388 | | 2021-03-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Acidosis (n/a - Unknown - ), Ascites (n/a - Unknown - Other Medically Important Condition), Atelectasis (n/a - Unknown - ), Cholelithiasis (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Enteritis (n/a - Unknown - ), Hypoglycaemia (n/a - Unknown - ), Ileus (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - ), Proctitis (n/a - Unknown - ), Retching (n/a - Unknown - ), Varices oesophageal (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21683 | click or scan EU-EC-10007978364 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21684 | click or scan EU-EC-10007978278 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Epilepsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21685 | click or scan EU-EC-10007978243 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21686 | click or scan EU-EC-10007978233 | | 2021-03-18 | Healthcare Professional | EEA | Not Specified | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Hyperglycaemia (n/a - Fatal - **Results in Death**), Hypernatraemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21687 | click or scan EU-EC-10007978122 | | 2021-03-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21688 | click or scan EU-EC-10007977917 | | 2021-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21689 | click or scan EU-EC-10007977505 | | 2021-03-18 | Healthcare Professional | EEA | 65-85 Years | Female | Aspiration (n/a - Fatal - **Results in Death**), Brain injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21690 | click or scan EU-EC-10007977227 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21691 | click or scan EU-EC-10007976480 | | 2021-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin discolouration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21692 | click or scan EU-EC-10007976293 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Communication disorder (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a]) |
| 21693 | click or scan EU-EC-10007976108 | | 2021-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21694 | click or scan EU-EC-10007975917 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1mL - Intramuscular]) |
| 21695 | click or scan EU-EC-10007975876 | | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Organ failure (3d - Fatal - **Results in Death**, Life Threatening), Pyrexia (3d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21696 | click or scan EU-EC-10007975667 | | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21697 | click or scan EU-EC-10007975503 |  | 2021-03-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1mL - Intramuscular]) |
| 21698 | click or scan EU-EC-10007975127 |  | 2021-03-18 | Healthcare Professional | EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21699 | click or scan EU-EC-10007975034 |  | 2021-03-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Muscle disorder (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21700 | click or scan EU-EC-10007974921 |  | 2021-03-18 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21701 | click or scan EU-EC-10007974917 |  | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21702 | click or scan EU-EC-10007974887 |  | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21703 | click or scan EU-EC-10007974848 |  | 2021-03-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21704 | click or scan EU-EC-10007974637 |  | 2021-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21705 | click or scan EU-EC-10007974612 |  | 2021-03-18 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21706 | click or scan EU-EC-10007974602 |  | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21707** | click or scan EU-EC-10007974549 |  | 2021-03-18 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **21708** | click or scan EU-EC-10007974517 |  | 2021-03-18 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Headache (2d - Recovered/Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **21709** | click or scan EU-EC-10007974496 |  | 2021-03-18 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21710** | click or scan EU-EC-10007974478 |  | 2021-03-18 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **21711** | click or scan EU-EC-10007974415 |  | 2021-03-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21712** | click or scan EU-EC-10007974157 |  | 2021-03-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **21713** | click or scan EU-EC-10007972715 |  | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Thrombotic microangiopathy (11d - Fatal - **Results in Death**), Thrombotic thrombocytopenic purpura (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [1d - n/a - n/a]) |
| **21714** | click or scan EU-EC-10007972150 |  | 2021-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **21715** | click or scan EU-EC-10007972125 |  | 2021-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| **21716** | click or scan EU-EC-10007971847 |  | 2021-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Venous oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21717 | click or scan EU-EC-10007971571 | | 2021-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - ), Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21718 | click or scan EU-EC-10007970629 | | 2021-03-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (1d - Recovered/Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21719 | click or scan EU-EC-10007970626 | | 2021-03-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21720 | click or scan EU-EC-10007970625 | | 2021-03-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Head injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21721 | click or scan EU-EC-10007970022 | | 2021-03-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21722 | click or scan EU-EC-10007969177 | | 2021-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21723 | click or scan EU-EC-10007968924 | | 2021-03-17 | Healthcare Professional | EEA | 18-64 Years | Female | Foreign body in throat (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 21724 | click or scan EU-EC-10007968795 | | 2021-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 21725 | click or scan EU-EC-10007968467 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21726 | click or scan EU-EC-10007968342 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21727 | click or scan EU-EC-10007968323 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21728 | click or scan EU-EC-10007968270 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive crisis (n/a - Recovering/Resolving - **Results in Death**, Other Medically Important Condition), Tremor (n/a - Recovering/Resolving - **Results in Death**, Other Medically Important Condition), Vertigo (n/a - Recovering/Resolving - **Results in Death**, Other Medically Important Condition), Visual impairment (n/a - Recovering/Resolving - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21729 | click or scan EU-EC-10007968215 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Eating disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 21730 | click or scan EU-EC-10007968083 | | 2021-03-17 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21731 | click or scan EU-EC-10007968080 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Face oedema (n/a - Unknown - **Results in Death**), Hypotension (n/a - Unknown - **Results in Death**), Oedema peripheral (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**), Tachycardia (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21732 | click or scan EU-EC-10007968075 | | 2021-03-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [CELIPROLOL HYDROCHLORIDE] (S - Myocardial ischaemia - Not applicable - [n/a - n/a - Oral]) |
| 21733 | click or scan EU-EC-10007968047 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperthermia (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21734 | click or scan EU-EC-10007967929 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]), [ACEBUTOLOL HYDROCHLORIDE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21735 | click or scan EU-EC-10007967876 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21736 | click or scan EU-EC-10007967732 | | 2021-03-17 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21737 | click or scan EU-EC-10007967542 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (0d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**), Tachycardia (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| 21738 | click or scan EU-EC-10007967457 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory distress (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [DIHYDROCODEINE TARTRATE] (S - Pain - Not applicable - [n/a - n/a - Oral]) |
| 21739 | click or scan EU-EC-10007967086 | | 2021-03-17 | Non Healthcare Professional | EEA | Not Specified | Male | Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21740 | click or scan EU-EC-10007966759 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21741 | click or scan EU-EC-10007966749 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21742 | click or scan EU-EC-10007966673 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Ischaemic stroke (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21743 | click or scan EU-EC-10007966627 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Respiratory distress (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| 21744 | click or scan EU-EC-10007966616 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| 21745 | click or scan EU-EC-10007966532 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21746 | click or scan EU-EC-10007966332 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 21747 | click or scan EU-EC-10007966309 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21748 | click or scan EU-EC-10007966181 |  | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Fall (n/a - Not Recovered/Not Resolved - **Results in Death**), Oxygen saturation abnormal (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21749 | click or scan EU-EC-10007966124 |  | 2021-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21750 | click or scan EU-EC-10007966049 |  | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21751 | click or scan EU-EC-10007965952 |  | 2021-03-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Illness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21752 | click or scan EU-EC-10007965885 |  | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 21753 | click or scan EU-EC-10007965621 |  | 2021-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21754 | click or scan EU-EC-10007965457 |  | 2021-03-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**), Peripheral vascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21755 | click or scan EU-EC-10007964748 |  | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (3d - Fatal - **Results in Death**), COVID-19 pneumonia (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21756 | click or scan EU-EC-10007964270 |  | 2021-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21757 | click or scan EU-EC-10007964268 |  | 2021-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21758 | click or scan EU-EC-10007964152 |  | 2021-03-17 | Healthcare Professional | Non EEA | Not Specified | Male | Death (7d - Fatal - **Results in Death**, Life Threatening), Nausea (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21759** | click or scan EU-EC-10007964148 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Hypertension (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - **Results in Death**), Tachypnoea (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **21760** | click or scan EU-EC-10007963274 | | 2021-03-17 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21761** | click or scan EU-EC-10007963151 | | 2021-03-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Fatal - **Results in Death**), Pyrexia (1d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Unknown - [n/a - 1mL - Intramuscular]) |
| **21762** | click or scan EU-EC-10007962505 | | 2021-03-17 | Healthcare Professional | EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21763** | click or scan EU-EC-10007960850 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| **21764** | click or scan EU-EC-10007960775 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **21765** | click or scan EU-EC-10007960766 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Dropped head syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**), Faecaloma (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21766** | click or scan EU-EC-10007960674 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21767** | click or scan EU-EC-10007960212 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21768** | click or scan EU-EC-10007960021 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21769 | click or scan EU-EC-10007959965 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21770 | click or scan EU-EC-10007959877 | | 2021-03-17 | Healthcare Professional | EEA | 18-64 Years | Female | Stress cardiomyopathy (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21771 | click or scan EU-EC-10007959858 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Diabetic coma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21772 | click or scan EU-EC-10007959822 | | 2021-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21773 | click or scan EU-EC-10007959811 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21774 | click or scan EU-EC-10007959790 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (0d - Fatal - **Results in Death**), Cyanosis (0d - Fatal - **Results in Death**), Hypopnoea (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21775 | click or scan EU-EC-10007959760 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (19d - Fatal - **Results in Death**), Agitation (19d - Fatal - **Results in Death**), General physical health deterioration (19d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]) |
| 21776 | click or scan EU-EC-10007959585 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21777 | click or scan EU-EC-10007959521 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21778 | click or scan EU-EC-10007959511 | | 2021-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21779 | click or scan EU-EC-10007959497 | | 2021-03-17 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21780 | click or scan EU-EC-10007959491 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Male | Dehydration (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (1d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21781 | click or scan EU-EC-10007959281 | | 2021-03-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21782 | click or scan EU-EC-10007958790 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21783 | click or scan EU-EC-10007958767 | | 2021-03-17 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| 21784 | click or scan EU-EC-10007958527 | | 2021-03-17 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21785 | click or scan EU-EC-10007958329 | | 2021-03-17 | Healthcare Professional | EEA | Not Specified | Male | Infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21786 | click or scan EU-EC-10007957402 | | 2021-03-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Delirium (n/a - Unknown - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21787 | click or scan EU-EC-10007956739 | | 2021-03-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21788 | click or scan EU-EC-10007954116 | | 2021-03-17 | Healthcare Professional | EEA | More than 85 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21789 | click or scan EU-EC-10007952243 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21790 | click or scan EU-EC-10007952167 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21791 | click or scan EU-EC-10007951925 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 21792 | click or scan EU-EC-10007951885 | | 2021-03-16 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21793 | click or scan EU-EC-10007951766 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 21794 | click or scan EU-EC-10007951675 | | 2021-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21795 | click or scan EU-EC-10007951530 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21796 | click or scan EU-EC-10007951488 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Hypersomnia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - n/a]) |
| 21797 | click or scan EU-EC-10007951319 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Atrioventricular block second degree (n/a - Unknown - ), Bradycardia (n/a - Unknown - ), Cardiac arrest (1d - Fatal - **Results in Death**, Life Threatening), Chest discomfort (n/a - Unknown - ), Nausea (n/a - Unknown - ), Retching (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - ), Ventricular fibrillation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Ventricular hypokinesia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21798 | click or scan EU-EC-10007951304 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Male | Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Melaena (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21799 | click or scan EU-EC-10007950940 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (17d - Fatal - **Results in Death**), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21800 | click or scan EU-EC-10007950762 | | 2021-03-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21801 | click or scan EU-EC-10007950633 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anxiety (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21802 | click or scan EU-EC-10007949527 | | 2021-03-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Personality change (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21803 | click or scan EU-EC-10007949279 | | 2021-03-16 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21804 | click or scan EU-EC-10007949271 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cognitive disorder (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21805 | click or scan EU-EC-10007949266 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21806 | click or scan EU-EC-10007949093 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (1d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (4d - Fatal - **Results in Death**), Oesophageal varices haemorrhage (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (0d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - n/a - [n/a - n/a - n/a]) |
| 21807 | click or scan EU-EC-10007948000 | | 2021-03-16 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1s - .5mL - Intramuscular]) |
| 21808 | click or scan EU-EC-10007947204 | | 2021-03-16 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21809 | click or scan EU-EC-10007947194 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21810** | click or scan EU-EC-10007947168 | | 2021-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21811** | click or scan EU-EC-10007946553 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21812** | click or scan EU-EC-10007946547 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21813** | click or scan EU-EC-10007946397 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21814** | click or scan EU-EC-10007946230 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21815** | click or scan EU-EC-10007946224 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **21816** | click or scan EU-EC-10007944984 | | 2021-03-16 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21817** | click or scan EU-EC-10007944887 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **21818** | click or scan EU-EC-10007944384 | | 2021-03-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure abnormal (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Lower respiratory tract congestion (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Respiratory disorder (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21819** | click or scan EU-EC-10007944128 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rales (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21820 | click or scan EU-EC-10007944037 | | 2021-03-16 | Healthcare Professional | EEA | Not Specified | Female | Bronchitis (n/a - Fatal - **Results in Death**), Organic brain syndrome (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21821 | click or scan EU-EC-10007943924 | | 2021-03-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (2d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21822 | click or scan EU-EC-10007943672 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21823 | click or scan EU-EC-10007943225 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Female | Pericardial haemorrhage (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21824 | click or scan EU-EC-10007943215 | | 2021-03-16 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21825 | click or scan EU-EC-10007943168 | | 2021-03-16 | Healthcare Professional | Non EEA | Not Specified | Female | Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21826 | click or scan EU-EC-10007943139 | | 2021-03-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 21827 | click or scan EU-EC-10007942845 | | 2021-03-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21828 | click or scan EU-EC-10007942472 | | 2021-03-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Vaccination site erythema (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vaccination site swelling (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21829 | click or scan EU-EC-10007942274 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21830** | click or scan EU-EC-10007942270 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **21831** | click or scan EU-EC-10007942255 | | 2021-03-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21832** | click or scan EU-EC-10007941059 | | 2021-03-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **21833** | click or scan EU-EC-10007939628 | | 2021-03-15 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **21834** | click or scan EU-EC-10007939326 | | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21835** | click or scan EU-EC-10007939325 | | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (9d - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21836** | click or scan EU-EC-10007939324 | | 2021-03-15 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (2d - Fatal - **Results in Death**, Life Threatening), Diarrhoea (2d - Fatal - **Results in Death**, Life Threatening), Vomiting (2d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21837** | click or scan EU-EC-10007938937 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dyskinesia (n/a - Unknown - ), Gait inability (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **21838** | click or scan EU-EC-10007938926 | | 2021-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **21839** | click or scan EU-EC-10007938839 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21840 | click or scan EU-EC-10007938700 | | 2021-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21841 | click or scan EU-EC-10007938533 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (2d - Fatal - **Results in Death**), Nausea (2d - Unknown - ), Vomiting (2d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 21842 | click or scan EU-EC-10007937846 | | 2021-03-15 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21843 | click or scan EU-EC-10007937180 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - ), Hypotension (1d - Fatal - **Results in Death**), Mental status changes (n/a - Unknown - ), Respiratory distress (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21844 | click or scan EU-EC-10007935605 | | 2021-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (1d - Fatal - **Results in Death**), Dysstasia (n/a - Not Recovered/Not Resolved - ), Gait inability (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Dose not changed - [n/a - 1 {DF} - Intramuscular]) |
| 21845 | click or scan EU-EC-10007935043 | | 2021-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (1d - Fatal - **Results in Death**), Chest pain (1d - Fatal - **Results in Death**), Pain (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21846 | click or scan EU-EC-10007935005 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21847 | click or scan EU-EC-10007934953 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Ageusia (9d - Unknown - ), Death (1d - Fatal - **Results in Death**), Decreased appetite (9d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21848 | click or scan EU-EC-10007934948 | | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21849 | click or scan EU-EC-10007934925 | | 2021-03-15 | Non Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21850 | click or scan EU-EC-10007934900 | | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21851 | click or scan EU-EC-10007934873 |  | 2021-03-15 | Healthcare Professional | EEA | 65-85 Years | Male | Headache (1d - Recovered/Resolved - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21852 | click or scan EU-EC-10007934867 |  | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21853 | click or scan EU-EC-10007934847 |  | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21854 | click or scan EU-EC-10007934748 |  | 2021-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21855 | click or scan EU-EC-10007934444 |  | 2021-03-15 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21856 | click or scan EU-EC-10007934340 |  | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Hypertension (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21857 | click or scan EU-EC-10007934179 |  | 2021-03-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), General physical condition abnormal (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21858 | click or scan EU-EC-10007933725 |  | 2021-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure like phenomena (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21859 | click or scan EU-EC-10007933096 |  | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Male | Epilepsy (1.5d - Fatal - **Results in Death**, Life Threatening), Escherichia sepsis (1.5d - Fatal - **Results in Death**, Life Threatening), Meningitis bacterial (1.5d - Fatal - **Results in Death**, Life Threatening), Pyrexia (1.5d - Fatal - **Results in Death**, Life Threatening), Somnolence (1.5d - Fatal - **Results in Death**, Life Threatening), Vomiting (1.5d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21860 | click or scan EU-EC-10007932753 |  | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21861 | click or scan EU-EC-10007932284 | | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21862 | click or scan EU-EC-10007931861 | | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21863 | click or scan EU-EC-10007931843 | | 2021-03-15 | Non Healthcare Professional | EEA | More than 85 Years | Female | Coordination abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Skin ulcer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21864 | click or scan EU-EC-10007931821 | | 2021-03-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21865 | click or scan EU-EC-10007931817 | | 2021-03-15 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21866 | click or scan EU-EC-10007931807 | | 2021-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 21867 | click or scan EU-EC-10007931687 | | 2021-03-15 | Non Healthcare Professional | EEA | Not Specified | Male | Blister infected (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21868 | click or scan EU-EC-10007930757 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (0d - Fatal - **Results in Death**), Cough (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21869 | click or scan EU-EC-10007930698 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21870 | click or scan EU-EC-10007930359 | | 2021-03-15 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21871** | click or scan EU-EC-10007930120 | | 2021-03-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung consolidation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **21872** | click or scan EU-EC-10007929881 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **21873** | click or scan EU-EC-10007929858 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Delirium (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Traumatic intracranial haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21874** | click or scan EU-EC-10007929524 | | 2021-03-15 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Illness (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21875** | click or scan EU-EC-10007928577 | | 2021-03-14 | Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (0d - Recovered/Resolved - ), Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **21876** | click or scan EU-EC-10007926948 | | 2021-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21877** | click or scan EU-EC-10007925273 | | 2021-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **21878** | click or scan EU-EC-10007924154 | | 2021-03-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **21879** | click or scan EU-EC-10007923964 | | 2021-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **21880** | click or scan EU-EC-10007922887 | | 2021-03-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Unknown - ), Death (n/a - Unknown - ), Swelling (3d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21881 | click or scan EU-EC-10007922833 | | 2021-03-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Life Threatening), Craniocerebral injury (n/a - Unknown - **Results in Death**, Life Threatening), Lower limb fracture (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 21882 | click or scan EU-EC-10007922014 | | 2021-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21883 | click or scan EU-EC-10007922008 | | 2021-03-14 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21884 | click or scan EU-EC-10007921975 | | 2021-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21885 | click or scan EU-EC-10007921330 | | 2021-03-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21886 | click or scan EU-EC-10007921321 | | 2021-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Lower respiratory tract infection (5d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21887 | click or scan EU-EC-10007920300 | | 2021-03-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Feeling of body temperature change (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 21888 | click or scan EU-EC-10007919801 | | 2021-03-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21889 | click or scan EU-EC-10007919179 | | 2021-03-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 21890 | click or scan EU-EC-10007918839 | | 2021-03-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21891 | click or scan EU-EC-10007914549 | | 2021-03-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Drooling (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Gait disturbance (n/a - Fatal - **Results in Death**), Lip swelling (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**), Oliguria (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**), Swollen tongue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21892 | click or scan EU-EC-10007913771 | | 2021-03-13 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 21893 | click or scan EU-EC-10007912356 | | 2021-03-13 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (9d - Fatal - **Results in Death**), Mesenteric vein thrombosis (9d - Fatal - **Results in Death**), Portal vein thrombosis (9d - Fatal - **Results in Death**), Pyrexia (9d - Fatal - **Results in Death**), Splenic vein thrombosis (9d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 21894 | click or scan EU-EC-10007909847 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21895 | click or scan EU-EC-10007909805 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21896 | click or scan EU-EC-10007909182 | | 2021-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| 21897 | click or scan EU-EC-10007908777 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21898 | click or scan EU-EC-10007908757 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Discomfort (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21899 | click or scan EU-EC-10007908625 | | 2021-03-12 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21900 | click or scan EU-EC-10007908622 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypersomnia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21901 | click or scan EU-EC-10007908506 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral small vessel ischaemic disease (14d - Fatal - **Results in Death**), Intestinal infarction (14d - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21902 | click or scan EU-EC-10007908419 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21903 | click or scan EU-EC-10007907794 | | 2021-03-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (1d - Unknown - ), Death (1d - Fatal - **Results in Death**), Wheezing (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21904 | click or scan EU-EC-10007907742 | | 2021-03-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (4d - Unknown - ), Death (n/a - Fatal - **Results in Death**), Diet refusal (4d - Unknown - ), Fluid intake reduced (4d - Unknown - ), General physical health deterioration (4d - Unknown - ), Haematemesis (4d - Unknown - ), Nausea (4d - Unknown - ), Vomiting (4d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21905 | click or scan EU-EC-10007907475 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21906 | click or scan EU-EC-10007906769 | | 2021-03-12 | Non Healthcare Professional | Non EEA | Not Specified | Male | Renal vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21907 | click or scan EU-EC-10007906099 | | 2021-03-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 21908 | click or scan EU-EC-10007905619 | | 2021-03-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21909 | click or scan EU-EC-10007905380 | | 2021-03-12 | Healthcare Professional | EEA | Not Specified | Male | Chills (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 21910 | click or scan EU-EC-10007905071 | | 2021-03-12 | Healthcare Professional | EEA | More than 85 Years | Female | Muscle spasms (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21911 | click or scan EU-EC-10007904573 | | 2021-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Sudden death (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21912** | click or scan EU-EC-10007903906 | | 2021-03-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | General physical health deterioration (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21913** | click or scan EU-EC-10007903790 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Diarrhoea (11d - Recovered/Resolved - ), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular]) |
| **21914** | click or scan EU-EC-10007903251 | | 2021-03-12 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure congestive (0d - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [1d - .3mL - Intramuscular]) |
| **21915** | click or scan EU-EC-10007902877 | | 2021-03-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **21916** | click or scan EU-EC-10007902506 | | 2021-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Bradykinesia (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Recovered/Resolved - ), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Recovered/Resolved - ), Haematemesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Head banging (n/a - Recovered/Resolved - ), Hypotension (30min - Recovered/Resolved - ), Pyrexia (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **21917** | click or scan EU-EC-10007902197 | | 2021-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | Diet refusal (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **21918** | click or scan EU-EC-10007901760 | | 2021-03-12 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21919** | click or scan EU-EC-10007901704 | | 2021-03-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bradycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypothermia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypothyroidism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21920 | click or scan EU-EC-10007901674 | | 2021-03-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Diet refusal (6d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21921 | click or scan EU-EC-10007901529 | | 2021-03-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Decreased appetite (n/a - Not Recovered/Not Resolved - ), Dehydration (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Mobility decreased (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [10min - 1 {DF} - Intramuscular]) |
| 21922 | click or scan EU-EC-10007901477 | | 2021-03-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 21923 | click or scan EU-EC-10007898302 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Lethargy (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21924 | click or scan EU-EC-10007898294 | | 2021-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal wall oedema (n/a - Unknown - ), Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ), Generalised oedema (n/a - Unknown - ), Hypotension (n/a - Unknown - ), Oedema (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21925 | click or scan EU-EC-10007898274 | | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21926 | click or scan EU-EC-10007898249 | | 2021-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21927 | click or scan EU-EC-10007897901 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 21928 | click or scan EU-EC-10007897815 | | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Craniocerebral injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21929 | click or scan EU-EC-10007897758 | | 2021-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21930 | click or scan EU-EC-10007897736 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coagulopathy (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **21931** | click or scan EU-EC-10007897564 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21932** | click or scan EU-EC-10007897491 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Brain injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulse absent (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **21933** | click or scan EU-EC-10007896719 | | 2021-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulse absent (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21934** | click or scan EU-EC-10007896195 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Tremor (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **21935** | click or scan EU-EC-10007896176 | | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apparent death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **21936** | click or scan EU-EC-10007896027 | | 2021-03-11 | Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dysuria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Flank pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematuria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Micturition urgency (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Scleral hyperaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **21937** | click or scan EU-EC-10007895786 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Lung infiltration (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **21938** | click or scan EU-EC-10007895667 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Drug resistance (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**), Vitamin D deficiency (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21939** | click or scan EU-EC-10007895666 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21940 | click or scan EU-EC-10007895621 | | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Incoherent (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Injection site pain (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Liver function test abnormal (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary retention (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21941 | click or scan EU-EC-10007895528 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Haemorrhage (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 21942 | click or scan EU-EC-10007895086 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 21943 | click or scan EU-EC-10007894973 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 21944 | click or scan EU-EC-10007894958 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Body temperature increased (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| 21945 | click or scan EU-EC-10007894949 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 21946 | click or scan EU-EC-10007894934 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Female | Hypothermia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21947 | click or scan EU-EC-10007894901 | | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulse absent (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21948 | click or scan EU-EC-10007894703 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21949 | click or scan EU-EC-10007894361 | | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic aneurysm (1d - Fatal - **Results in Death**), Arteriosclerosis (1d - Fatal - **Results in Death**), Asthenia (n/a - Unknown - ), Cardiac arrest (1d - Fatal - **Results in Death**), Hyperhidrosis (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21950** | click or scan EU-EC-10007894360 |  | 2021-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Death (1d - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **21951** | click or scan EU-EC-10007894021 |  | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **21952** | click or scan EU-EC-10007893940 |  | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **21953** | click or scan EU-EC-10007893389 |  | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21954** | click or scan EU-EC-10007892898 |  | 2021-03-11 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21955** | click or scan EU-EC-10007892861 |  | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **21956** | click or scan EU-EC-10007892489 |  | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21957** | click or scan EU-EC-10007892484 |  | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21958** | click or scan EU-EC-10007892466 |  | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **21959** | click or scan EU-EC-10007892455 |  | 2021-03-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21960 | click or scan EU-EC-10007891990 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21961 | click or scan EU-EC-10007891956 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 21962 | click or scan EU-EC-10007891400 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 21963 | click or scan EU-EC-10007889689 | | 2021-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Flatulence (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21964 | click or scan EU-EC-10007889672 | | 2021-03-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 21965 | click or scan EU-EC-10007889472 | | 2021-03-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 21966 | click or scan EU-EC-10007889445 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Electrocardiogram ST segment depression (n/a - Fatal - **Results in Death**), Escherichia pyelonephritis (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Supraventricular tachycardia (n/a - Fatal - **Results in Death**), Troponin I increased (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a]) |
| 21967 | click or scan EU-EC-10007889440 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), Cerebral infarction (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 21968 | click or scan EU-EC-10007889059 | | 2021-03-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain stem syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 21969 | click or scan EU-EC-10007889044 | | 2021-03-11 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 21970 | click or scan EU-EC-10007888752 | | 2021-03-11 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21971 | click or scan EU-EC-10007888722 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21972 | click or scan EU-EC-10007888638 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 21973 | click or scan EU-EC-10007888556 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cholecystitis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21974 | click or scan EU-EC-10007888494 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 21975 | click or scan EU-EC-10007888459 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Male | Aneurysm ruptured (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 21976 | click or scan EU-EC-10007888371 | | 2021-03-11 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 21977 | click or scan EU-EC-10007888269 | | 2021-03-11 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 21978 | click or scan EU-EC-10007886172 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Vomiting (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| 21979 | click or scan EU-EC-10007886109 | | 2021-03-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **21980** | click or scan EU-EC-10007886081 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21981** | click or scan EU-EC-10007885998 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bladder cancer stage IV (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21982** | click or scan EU-EC-10007885978 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic aneurysm rupture (1d - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **21983** | click or scan EU-EC-10007885951 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Discomfort (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **21984** | click or scan EU-EC-10007885716 | | 2021-03-10 | Healthcare Professional | EEA | 18-64 Years | Male | Acute respiratory failure (1d - Fatal - **Results in Death**), Depressed level of consciousness (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown]) |
| **21985** | click or scan EU-EC-10007885683 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **21986** | click or scan EU-EC-10007885574 | | 2021-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abnormal behaviour (n/a - Unknown - ), Agonal rhythm (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Unknown - ), Erythema (n/a - Unknown - ), Pain (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21987** | click or scan EU-EC-10007885560 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21988** | click or scan EU-EC-10007885502 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **21989** | click or scan EU-EC-10007885474 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **21990** | click or scan EU-EC-10007885472 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 21991 | click or scan EU-EC-10007885427 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 21992 | click or scan EU-EC-10007885037 | | 2021-03-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Unevaluable event (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 21993 | click or scan EU-EC-10007884396 | | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 21994 | click or scan EU-EC-10007884353 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 21995 | click or scan EU-EC-10007883824 | | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 21996 | click or scan EU-EC-10007883796 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 21997 | click or scan EU-EC-10007883653 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 21998 | click or scan EU-EC-10007883357 | | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 21999 | click or scan EU-EC-10007881945 | | 2021-03-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 22000 | click or scan EU-EC-10007881452 | | 2021-03-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Body temperature decreased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22001 | click or scan EU-EC-10007881065 |  | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 22002 | click or scan EU-EC-10007881019 |  | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Agitation (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Bacterial sepsis (n/a - Fatal - **Results in Death**), Body temperature increased (n/a - Recovered/Resolved - ), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Disorientation (n/a - Not Recovered/Not Resolved - ), Fall (n/a - Not Recovered/Not Resolved - ), Gait disturbance (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Somnolence (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22003 | click or scan EU-EC-10007880827 |  | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Unknown - ), Abdominal pain upper (n/a - Unknown - ), Cholecystectomy (1d - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pancreatitis acute (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22004 | click or scan EU-EC-10007880678 |  | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22005 | click or scan EU-EC-10007880676 |  | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22006 | click or scan EU-EC-10007880675 |  | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22007 | click or scan EU-EC-10007880196 |  | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22008 | click or scan EU-EC-10007879917 |  | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a]) |
| 22009 | click or scan EU-EC-10007878996 |  | 2021-03-10 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22010 | click or scan EU-EC-10007878883 |  | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22011 | click or scan EU-EC-10007878664 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Vomiting (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| 22012 | click or scan EU-EC-10007878394 | | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 22013 | click or scan EU-EC-10007878009 | | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22014 | click or scan EU-EC-10007877723 | | 2021-03-10 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22015 | click or scan EU-EC-10007876975 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22016 | click or scan EU-EC-10007876482 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical condition abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22017 | click or scan EU-EC-10007875653 | | 2021-03-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22018 | click or scan EU-EC-10007875182 | | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22019 | click or scan EU-EC-10007875172 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Bronchopneumopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22020 | click or scan EU-EC-10007874918 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 22021 | click or scan EU-EC-10007874843 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22022 | click or scan EU-EC-10007874776 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Male | Hypoxia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 22023 | click or scan EU-EC-10007874325 | | 2021-03-10 | Healthcare Professional | EEA | 65-85 Years | Female | Pemphigoid (20d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (S - Depression - Dose not changed - [n/a - 37.5mg - Oral]) |
| 22024 | click or scan EU-EC-10007874288 | | 2021-03-10 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22025 | click or scan EU-EC-10007874237 | | 2021-03-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22026 | click or scan EU-EC-10007871028 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Chills (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (1d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22027 | click or scan EU-EC-10007870906 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22028 | click or scan EU-EC-10007870400 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22029 | click or scan EU-EC-10007870332 | | 2021-03-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22030 | click or scan EU-EC-10007870307 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**, Life Threatening), Endotracheal intubation (2d - Unknown - ), Myoclonus (2d - Unknown - ), Resuscitation (2d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 22031 | click or scan EU-EC-10007870301 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Presyncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22032** | click or scan EU-EC-10007870293 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Medical device site haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22033** | click or scan EU-EC-10007870173 | | 2021-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22034** | click or scan EU-EC-10007870153 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22035** | click or scan EU-EC-10007870117 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22036** | click or scan EU-EC-10007870113 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (9d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (9d - Fatal - **Results in Death**), Dyspnoea exertional (9d - Fatal - **Results in Death**), Fatigue (9d - Fatal - **Results in Death**), Lethargy (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22037** | click or scan EU-EC-10007870081 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Weight decreased (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22038** | click or scan EU-EC-10007869528 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Asthenia (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Lividity (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **22039** | click or scan EU-EC-10007869458 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **22040** | click or scan EU-EC-10007869424 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22041** | click or scan EU-EC-10007869111 | | 2021-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22042 | click or scan EU-EC-10007868983 |  | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Immune thrombocytopenia (10d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [GLYCERYL TRINITRATE] (I - Product used for unknown indication - n/a - [n/a - .4mg - n/a]) |
| 22043 | click or scan EU-EC-10007868759 |  | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agonal rhythm (n/a - Unknown - Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Heart rate irregular (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22044 | click or scan EU-EC-10007868503 |  | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22045 | click or scan EU-EC-10007868425 |  | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22046 | click or scan EU-EC-10007868246 |  | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22047 | click or scan EU-EC-10007868238 |  | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22048 | click or scan EU-EC-10007868191 |  | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Recovered/Resolved - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22049 | click or scan EU-EC-10007868041 |  | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Obstructive pancreatitis (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22050 | click or scan EU-EC-10007868009 |  | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22051 | click or scan EU-EC-10007868003 |  | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22052** | click or scan EU-EC-10007867942 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22053** | click or scan EU-EC-10007867709 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (n/a - Not Recovered/Not Resolved - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Not Recovered/Not Resolved - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Unknown - ), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Not Recovered/Not Resolved - ), Productive cough (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| **22054** | click or scan EU-EC-10007867380 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| **22055** | click or scan EU-EC-10007867254 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Incorrect route of product administration (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intradermal]) |
| **22056** | click or scan EU-EC-10007867235 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aspiration pleural cavity (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staring (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22057** | click or scan EU-EC-10007867170 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22058** | click or scan EU-EC-10007867046 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - ), Subdural haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22059** | click or scan EU-EC-10007867019 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Unknown - ), Death (3d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22060** | click or scan EU-EC-10007866743 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), General physical health deterioration (13d - Fatal - **Results in Death**), Hypersomnia (n/a - Unknown - ), Moaning (n/a - Unknown - ), Pain (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Wound secretion (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22061** | click or scan EU-EC-10007866700 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22062** | click or scan EU-EC-10007866666 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22063** | click or scan EU-EC-10007866653 | | 2021-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22064** | click or scan EU-EC-10007866634 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22065** | click or scan EU-EC-10007866329 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Subdural haematoma (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22066** | click or scan EU-EC-10007866134 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22067** | click or scan EU-EC-10007865939 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22068** | click or scan EU-EC-10007865871 | | 2021-03-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Other Medically Important Condition), Hiatus hernia (n/a - Unknown - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Metabolic acidosis (n/a - Not Recovered/Not Resolved - ), Nodal rhythm (n/a - Recovered/Resolved - ), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **22069** | click or scan EU-EC-10007865345 | | 2021-03-09 | Healthcare Professional | EEA | 18-64 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ascites (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia induced cardiomyopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22070** | click or scan EU-EC-10007865223 | | 2021-03-09 | Healthcare Professional | EEA | 18-64 Years | Male | Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22071 | click or scan EU-EC-10007864731 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspepsia (n/a - Not Recovered/Not Resolved - **Results in Death**), Feeling hot (n/a - Not Recovered/Not Resolved - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22072 | click or scan EU-EC-10007864662 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (4d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (1d - Unknown - **Results in Death**, Other Medically Important Condition), Hypertension (1d - Unknown - **Results in Death**, Other Medically Important Condition), Tachycardia (3d - Unknown - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22073 | click or scan EU-EC-10007864521 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | INLYTA [AXITINIB] (S - Renal cancer - Dose not changed - [n/a - 3mg - Oral]), KEYTRUDA [PEMBROLIZUMAB] (S - Renal cancer - Dose not changed - [n/a - n/a - Intravenous drip]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Dyslipidaemia - Dose not changed - [n/a - 40mg - Oral]), [COLECALCIFEROL] (S - Vitamin supplementation - Dose not changed - [n/a - 1 {DF} - Oral]), [LERCANIDIPINE HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 20mg - Oral]) |
| 22074 | click or scan EU-EC-10007864492 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperthermia (n/a - Recovered/Resolved - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22075 | click or scan EU-EC-10007863925 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | Ischaemic stroke (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mg - Intramuscular]) |
| 22076 | click or scan EU-EC-10007863891 | | 2021-03-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mg - Intramuscular]) |
| 22077 | click or scan EU-EC-10007863518 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Hypotension (n/a - Recovering/Resolving - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22078 | click or scan EU-EC-10007863266 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22079 | click or scan EU-EC-10007862787 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhage (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular]) |
| 22080 | click or scan EU-EC-10007862664 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | INLYTA [AXITINIB] (S - Renal cancer - Not applicable - [n/a - 3mg - Oral]), KEYTRUDA [PEMBROLIZUMAB] (S - Renal cancer - Not applicable - [n/a - 200mg - Intravenous drip]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22081 | click or scan EU-EC-10007862227 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| 22082 | click or scan EU-EC-10007862225 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Male | Oxygen saturation decreased (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| 22083 | click or scan EU-EC-10007862220 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| 22084 | click or scan EU-EC-10007862217 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| 22085 | click or scan EU-EC-10007862001 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22086 | click or scan EU-EC-10007861802 | | 2021-03-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Lower respiratory tract congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung abscess (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22087 | click or scan EU-EC-10007861689 | | 2021-03-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22088 | click or scan EU-EC-10007861676 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (24d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22089 | click or scan EU-EC-10007861668 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (21d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22090 | click or scan EU-EC-10007861582 | | 2021-03-09 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22091 | click or scan EU-EC-10007861540 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22092 | click or scan EU-EC-10007861224 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22093 | click or scan EU-EC-10007860270 | | 2021-03-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22094 | click or scan EU-EC-10007859873 | | 2021-03-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Unknown - ), Back pain (n/a - Unknown - ), Coronavirus test positive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Pyrexia (5d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22095 | click or scan EU-EC-10007859715 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22096 | click or scan EU-EC-10007859517 | | 2021-03-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dysphagia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22097 | click or scan EU-EC-10007858733 | | 2021-03-09 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**), Productive cough (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 22098 | click or scan EU-EC-10007857499 | | 2021-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22099 | click or scan EU-EC-10007857430 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cognitive disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22100 | click or scan EU-EC-10007857398 | | 2021-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22101 | click or scan EU-EC-10007857364 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22102 | click or scan EU-EC-10007857353 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiomyopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22103 | click or scan EU-EC-10007857293 | | 2021-03-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | Blue toe syndrome (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown - ), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - ), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - ), Skin discolouration (n/a - Unknown - ), Tremor (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22104 | click or scan EU-EC-10007857264 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22105 | click or scan EU-EC-10007857240 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22106 | click or scan EU-EC-10007857198 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22107 | click or scan EU-EC-10007856908 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (2d - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (2d - Fatal - **Results in Death**), Hip fracture (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22108 | click or scan EU-EC-10007856762 | | 2021-03-08 | Healthcare Professional | Non EEA | Not Specified | Female | Immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22109 | click or scan EU-EC-10007856680 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Hyperventilation (n/a - Unknown - ), Muscle rigidity (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22110 | click or scan EU-EC-10007856572 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22111 | click or scan EU-EC-10007856556 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22112 | click or scan EU-EC-10007856535 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22113 | click or scan EU-EC-10007856527 | | 2021-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bone fragmentation (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Road traffic accident (n/a - Fatal - **Results in Death**), Spinal compression fracture (n/a - Fatal - **Results in Death**), Spinal stenosis (n/a - Fatal - **Results in Death**), Subdural haematoma (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22114 | click or scan EU-EC-10007856235 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22115 | click or scan EU-EC-10007856056 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22116 | click or scan EU-EC-10007856013 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22117 | click or scan EU-EC-10007855849 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - ), Head injury (n/a - Unknown - ), Injection site ulcer (n/a - Unknown - ), Malaise (n/a - Unknown - ), Neck pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22118 | click or scan EU-EC-10007855458 | | 2021-03-08 | Non Healthcare Professional | EEA | Not Specified | Female | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22119 | click or scan EU-EC-10007855456 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22120 | click or scan EU-EC-10007855453 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Vascular dementia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22121 | click or scan EU-EC-10007855299 | | 2021-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22122 | click or scan EU-EC-10007855292 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22123 | click or scan EU-EC-10007855182 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22124 | click or scan EU-EC-10007855081 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22125 | click or scan EU-EC-10007854735 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22126 | click or scan EU-EC-10007854709 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cough (1d - Fatal - **Results in Death**), Increased bronchial secretion (1d - Fatal - **Results in Death**), Productive cough (1d - Fatal - **Results in Death**), Rhinorrhoea (1d - Fatal - **Results in Death**), Secretion discharge (1d - Fatal - **Results in Death**), Swelling face (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22127 | click or scan EU-EC-10007854640 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Disorientation (n/a - Unknown - ), Fall (n/a - Unknown - ), Pruritus (n/a - Unknown - ), Swelling (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22128 | click or scan EU-EC-10007854460 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Immobile (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22129 | click or scan EU-EC-10007854316 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Life Threatening), Death (1d - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22130 | click or scan EU-EC-10007853884 | | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22131 | click or scan EU-EC-10007853867 | | 2021-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22132 | click or scan EU-EC-10007853323 | | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Conjunctival oedema (n/a - Fatal - **Results in Death**), Lip swelling (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Mouth swelling (n/a - Fatal - **Results in Death**), Peripheral swelling (n/a - Fatal - **Results in Death**), Swelling face (n/a - Fatal - **Results in Death**), Swollen tongue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22133 | click or scan EU-EC-10007853168 | | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (0d - Recovering/Resolving - ), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22134 | click or scan EU-EC-10007853159 | | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (n/a - Recovering/Resolving - ), Chills (1d - Recovered/Resolved - ), Fatigue (1d - Recovered/Resolved - ), Hepatitis C (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22135 | click or scan EU-EC-10007853156 | | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22136 | click or scan EU-EC-10007853137 | | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22137 | click or scan EU-EC-10007853115 | | 2021-03-08 | Healthcare Professional | EEA | Not Specified | Male | Body temperature increased (n/a - Unknown - ), Cardiac disorder (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22138 | click or scan EU-EC-10007853107 | | 2021-03-08 | Non Healthcare Professional | EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22139 | click or scan EU-EC-10007853096 | | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22140 | click or scan EU-EC-10007853082 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22141 | click or scan EU-EC-10007852907 | | 2021-03-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22142 | click or scan EU-EC-10007852817 | | 2021-03-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiovascular disorder (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22143 | click or scan EU-EC-10007852816 | | 2021-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiovascular disorder (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Respiratory disorder (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22144 | click or scan EU-EC-10007852815 | | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22145 | click or scan EU-EC-10007851949 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22146 | click or scan EU-EC-10007851423 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22147 | click or scan EU-EC-10007850739 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22148 | click or scan EU-EC-10007850737 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22149 | click or scan EU-EC-10007850721 | | 2021-03-08 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22150 | click or scan EU-EC-10007850528 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Electrolyte depletion (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22151 | click or scan EU-EC-10007850420 |  | 2021-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22152 | click or scan EU-EC-10007850328 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22153 | click or scan EU-EC-10007850264 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22154 | click or scan EU-EC-10007850261 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dementia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22155 | click or scan EU-EC-10007850259 |  | 2021-03-08 | Non Healthcare Professional | EEA | Not Specified | Not Specified | COVID-19 (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 22156 | click or scan EU-EC-10007850257 |  | 2021-03-08 | Non Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22157 | click or scan EU-EC-10007850256 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22158 | click or scan EU-EC-10007850255 |  | 2021-03-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22159 | click or scan EU-EC-10007850254 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (3d - Fatal - **Results in Death**), COVID-19 (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 22160 | click or scan EU-EC-10007850248 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22161 | click or scan EU-EC-10007850245 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 22162 | click or scan EU-EC-10007850244 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22163 | click or scan EU-EC-10007850243 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22164 | click or scan EU-EC-10007850235 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Apathy (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 22165 | click or scan EU-EC-10007850231 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22166 | click or scan EU-EC-10007850229 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - ), Cerebral infarction (11d - Fatal - **Results in Death**), Hemiparesis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 22167 | click or scan EU-EC-10007850228 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22168 | click or scan EU-EC-10007850227 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dehydration (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Gastrointestinal pain (n/a - Unknown - ), Nausea (n/a - Unknown - ), Oliguria (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22169 | click or scan EU-EC-10007850226 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Lethargy (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22170 | click or scan EU-EC-10007850224 |  | 2021-03-08 | Non Healthcare Professional | EEA | Not Specified | Female | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dysphonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 22171 | click or scan EU-EC-10007850222 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Gait inability (n/a - Not Recovered/Not Resolved - ), Quadriparesis (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22172 | click or scan EU-EC-10007850221 | | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Bedridden (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22173 | click or scan EU-EC-10007850219 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22174 | click or scan EU-EC-10007850217 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22175 | click or scan EU-EC-10007850212 | | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22176 | click or scan EU-EC-10007850211 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22177 | click or scan EU-EC-10007850202 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (1d - Fatal - **Results in Death**), Haemoglobin decreased (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22178 | click or scan EU-EC-10007850200 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22179 | click or scan EU-EC-10007850196 | | 2021-03-08 | Non Healthcare Professional | EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 22180 | click or scan EU-EC-10007850192 | | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Pneumonia (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 22181 | click or scan EU-EC-10007850191 | | 2021-03-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Respiratory failure (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22182 | click or scan EU-EC-10007850188 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22183 | click or scan EU-EC-10007850187 |  | 2021-03-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asymptomatic COVID-19 (n/a - Unknown - ), Respiratory distress (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22184 | click or scan EU-EC-10007850179 |  | 2021-03-08 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaphylactic reaction (0d - Fatal - **Results in Death**), Respiratory distress (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22185 | click or scan EU-EC-10007850162 |  | 2021-03-08 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22186 | click or scan EU-EC-10007850085 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22187 | click or scan EU-EC-10007850083 |  | 2021-03-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Cranial nerve decompression (n/a - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22188 | click or scan EU-EC-10007849887 |  | 2021-03-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Not Recovered/Not Resolved - ), Pyrexia (3d - Recovered/Resolved - ), Vomiting (2d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22189 | click or scan EU-EC-10007849163 |  | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22190 | click or scan EU-EC-10007848934 |  | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22191 | click or scan EU-EC-10007848907 |  | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22192** | click or scan EU-EC-10007848073 | | 2021-03-08 | Healthcare Professional | EEA | 65-85 Years | Male | Acute abdomen (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **22193** | click or scan EU-EC-10007848072 | | 2021-03-08 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22194** | click or scan EU-EC-10007847808 | | 2021-03-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **22195** | click or scan EU-EC-10007847612 | | 2021-03-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **22196** | click or scan EU-EC-10007846442 | | 2021-03-08 | Non Healthcare Professional | Non EEA | Not Specified | Male | Asymptomatic COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **22197** | click or scan EU-EC-10007842943 | | 2021-03-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22198** | click or scan EU-EC-10007840224 | | 2021-03-07 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22199** | click or scan EU-EC-10007840139 | | 2021-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22200** | click or scan EU-EC-10007838811 | | 2021-03-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **22201** | click or scan EU-EC-10007833706 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22202** | click or scan EU-EC-10007833623 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22203** | click or scan EU-EC-10007832037 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **22204** | click or scan EU-EC-10007832034 | | 2021-03-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **22205** | click or scan EU-EC-10007831208 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **22206** | click or scan EU-EC-10007831157 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22207** | click or scan EU-EC-10007831132 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22208** | click or scan EU-EC-10007831131 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22209** | click or scan EU-EC-10007831130 | | 2021-03-06 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **22210** | click or scan EU-EC-10007831124 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **22211** | click or scan EU-EC-10007831122 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arteriosclerosis (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - **Results in Death**), Myocardial ischaemia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **22212** | click or scan EU-EC-10007830636 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22213 | click or scan EU-EC-10007827141 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22214 | click or scan EU-EC-10007827040 | | 2021-03-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22215 | click or scan EU-EC-10007827032 | | 2021-03-06 | Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 22216 | click or scan EU-EC-10007826812 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22217 | click or scan EU-EC-10007826807 | | 2021-03-06 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22218 | click or scan EU-EC-10007826800 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 22219 | click or scan EU-EC-10007826795 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Deep vein thrombosis (n/a - Unknown - **Results in Death**), Lethargy (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Unknown - **Results in Death**), Pulmonary infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22220 | click or scan EU-EC-10007825424 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22221 | click or scan EU-EC-10007825267 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22222 | click or scan EU-EC-10007825257 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22223 | click or scan EU-EC-10007825255 |  | 2021-03-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22224 | click or scan EU-EC-10007825254 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 22225 | click or scan EU-EC-10007825253 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22226 | click or scan EU-EC-10007825252 |  | 2021-03-06 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 22227 | click or scan EU-EC-10007825250 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Dose not changed - [n/a - 500uL - n/a]) |
| 22228 | click or scan EU-EC-10007825241 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 22229 | click or scan EU-EC-10007825238 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 22230 | click or scan EU-EC-10007825057 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22231 | click or scan EU-EC-10007825043 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22232 | click or scan EU-EC-10007825029 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22233 | click or scan EU-EC-10007825014 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22234 | click or scan EU-EC-10007825011 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22235 | click or scan EU-EC-10007825008 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22236 | click or scan EU-EC-10007825006 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22237 | click or scan EU-EC-10007825004 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22238 | click or scan EU-EC-10007825003 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22239 | click or scan EU-EC-10007825002 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22240 | click or scan EU-EC-10007825001 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22241 | click or scan EU-EC-10007824993 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22242 | click or scan EU-EC-10007823979 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22243 | click or scan EU-EC-10007823135 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22244 | click or scan EU-EC-10007820612 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22245 | click or scan EU-EC-10007819700 | | 2021-03-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22246 | click or scan EU-EC-10007819626 | | 2021-03-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22247 | click or scan EU-EC-10007819613 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - **Results in Death**), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 22248 | click or scan EU-EC-10007819583 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22249 | click or scan EU-EC-10007819565 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22250 | click or scan EU-EC-10007819560 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22251 | click or scan EU-EC-10007818903 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Ill-defined disorder - Unknown - [n/a - n/a - n/a]) |
| 22252 | click or scan EU-EC-10007818799 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22253** | click or scan EU-EC-10007818566 | | 2021-03-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Sepsis (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22254** | click or scan EU-EC-10007818143 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22255** | click or scan EU-EC-10007817535 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22256** | click or scan EU-EC-10007817146 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22257** | click or scan EU-EC-10007816582 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22258** | click or scan EU-EC-10007816563 | | 2021-03-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Aspiration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22259** | click or scan EU-EC-10007815991 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **22260** | click or scan EU-EC-10007815888 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22261** | click or scan EU-EC-10007815766 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dehydration (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22262** | click or scan EU-EC-10007815738 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **22263** | click or scan EU-EC-10007815530 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute cardiac event (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22264 | click or scan EU-EC-10007815474 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22265 | click or scan EU-EC-10007815089 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22266 | click or scan EU-EC-10007814746 |  | 2021-03-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22267 | click or scan EU-EC-10007814539 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22268 | click or scan EU-EC-10007814477 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22269 | click or scan EU-EC-10007814229 |  | 2021-03-06 | Healthcare Professional | Non EEA | Not Specified | Male | Urosepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22270 | click or scan EU-EC-10007813575 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22271 | click or scan EU-EC-10007813510 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22272 | click or scan EU-EC-10007813493 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22273 | click or scan EU-EC-10007813455 |  | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (9h - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a]) |
| 22274 | click or scan EU-EC-10007813261 |  | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22275 | click or scan EU-EC-10007813260 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22276 | click or scan EU-EC-10007813181 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22277 | click or scan EU-EC-10007813106 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22278 | click or scan EU-EC-10007812922 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22279 | click or scan EU-EC-10007812865 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22280 | click or scan EU-EC-10007812811 | | 2021-03-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22281 | click or scan EU-EC-10007812792 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22282 | click or scan EU-EC-10007812766 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22283 | click or scan EU-EC-10007812679 | | 2021-03-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 22284 | click or scan EU-EC-10007810173 | | 2021-03-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal distension (3d - Unknown - ), Cardio-respiratory arrest (3d - Unknown - Life Threatening), Death (3d - Fatal - **Results in Death**), Decreased appetite (3d - Unknown - ), Fatigue (3d - Unknown - ), Feeling abnormal (3d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| 22285 | click or scan EU-EC-10007810060 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22286 | click or scan EU-EC-10007810048 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22287 | click or scan EU-EC-10007810001 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22288 | click or scan EU-EC-10007809961 | | 2021-03-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acidosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Encephalopathy (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22289 | click or scan EU-EC-10007809936 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22290 | click or scan EU-EC-10007809923 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22291 | click or scan EU-EC-10007809900 | | 2021-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22292 | click or scan EU-EC-10007809838 | | 2021-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22293 | click or scan EU-EC-10007809810 | | 2021-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure congestive (2d - Fatal - **Results in Death**), Cardiomegaly (2d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Feeling hot (2d - Fatal - **Results in Death**), Hiatus hernia (2d - Fatal - **Results in Death**), Hypoxia (2d - Fatal - **Results in Death**), Leukocytosis (2d - Fatal - **Results in Death**), Pleural effusion (2d - Fatal - **Results in Death**), Pulmonary oedema (2d - Fatal - **Results in Death**), Pulmonary vascular disorder (2d - Fatal - **Results in Death**), Renal failure (2d - Fatal - **Results in Death**), Spinal fracture (2d - Fatal - **Results in Death**), Urinary tract infection (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**), White blood cell disorder (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22294 | click or scan EU-EC-10007809464 | | 2021-03-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22295 | click or scan EU-EC-10007809458 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22296 | click or scan EU-EC-10007809457 | | 2021-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bundle branch block left (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22297 | click or scan EU-EC-10007809373 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pain in jaw (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 22298 | click or scan EU-EC-10007809368 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22299 | click or scan EU-EC-10007809354 | | 2021-03-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**), Fatigue (1d - Unknown - ), Pain in extremity (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22300 | click or scan EU-EC-10007809139 | | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Depressed mood (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22301 | click or scan EU-EC-10007808974 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Retching (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22302 | click or scan EU-EC-10007808605 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22303 | click or scan EU-EC-10007808587 | | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Vascular dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22304 | click or scan EU-EC-10007808535 | | 2021-03-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Immunodeficiency (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22305 | click or scan EU-EC-10007807667 |  | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22306 | click or scan EU-EC-10007807356 |  | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pericarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22307 | click or scan EU-EC-10007807240 |  | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22308 | click or scan EU-EC-10007807239 |  | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22309 | click or scan EU-EC-10007806533 |  | 2021-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haemorrhagic stroke (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22310 | click or scan EU-EC-10007806532 |  | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22311 | click or scan EU-EC-10007806388 |  | 2021-03-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 22312 | click or scan EU-EC-10007806375 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a]) |
| 22313 | click or scan EU-EC-10007805898 |  | 2021-03-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (20d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (20d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Respiratory failure (20d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22314 | click or scan EU-EC-10007805860 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22315 | click or scan EU-EC-10007805365 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22316 | click or scan EU-EC-10007805208 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (n/a - Not Recovered/Not Resolved - Life Threatening), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Life Threatening), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22317 | click or scan EU-EC-10007804663 |  | 2021-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition), Vascular dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22318 | click or scan EU-EC-10007803283 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 22319 | click or scan EU-EC-10007803277 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 22320 | click or scan EU-EC-10007803265 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 22321 | click or scan EU-EC-10007803222 |  | 2021-03-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Coma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Oesophageal varices haemorrhage (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22322 | click or scan EU-EC-10007803157 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 22323 | click or scan EU-EC-10007803008 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22324 | click or scan EU-EC-10007802977 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22325** | click or scan EU-EC-10007802971 |  | 2021-03-05 | Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22326** | click or scan EU-EC-10007802954 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22327** | click or scan EU-EC-10007802948 |  | 2021-03-05 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22328** | click or scan EU-EC-10007802911 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22329** | click or scan EU-EC-10007802890 |  | 2021-03-05 | Non Healthcare Professional | EEA | Not Specified | Female | Dehydration (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22330** | click or scan EU-EC-10007802146 |  | 2021-03-05 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22331** | click or scan EU-EC-10007802046 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Dizziness (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22332** | click or scan EU-EC-10007801138 |  | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22333** | click or scan EU-EC-10007801089 |  | 2021-03-05 | Healthcare Professional | EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22334** | click or scan EU-EC-10007801008 |  | 2021-03-05 | Healthcare Professional | EEA | 65-85 Years | Female | Fatigue (n/a - Unknown - ), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22335 | click or scan EU-EC-10007799929 | | 2021-03-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22336 | click or scan EU-EC-10007798774 | | 2021-03-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pain (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22337 | click or scan EU-EC-10007798450 | | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Dehydration (4d - Fatal - **Results in Death**, Life Threatening), Disturbance in attention (4d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (4d - Fatal - **Results in Death**, Life Threatening), Pneumonia bacterial (4d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22338 | click or scan EU-EC-10007798396 | | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22339 | click or scan EU-EC-10007798312 | | 2021-03-05 | Healthcare Professional | EEA | 65-85 Years | Male | Dehydration (3d - Fatal - **Results in Death**, Life Threatening), Disturbance in attention (3d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (3d - Fatal - **Results in Death**, Life Threatening), Pneumonia bacterial (3d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22340 | click or scan EU-EC-10007798247 | | 2021-03-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (0d - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22341 | click or scan EU-EC-10007798210 | | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disturbance in attention (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epilepsy (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical condition abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercalcaemia (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 22342 | click or scan EU-EC-10007797264 | | 2021-03-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22343 | click or scan EU-EC-10007797071 | | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 22344 | click or scan EU-EC-10007796252 | | 2021-03-05 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22345 | click or scan EU-EC-10007796932 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Intracranial aneurysm (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22346 | click or scan EU-EC-10007795253 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22347 | click or scan EU-EC-10007795215 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22348 | click or scan EU-EC-10007794847 | | 2021-03-04 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - 1 {DF} - Unknown]) |
| 22349 | click or scan EU-EC-10007794752 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22350 | click or scan EU-EC-10007794748 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22351 | click or scan EU-EC-10007794636 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atelectasis (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Hypotension (2d - Fatal - **Results in Death**), Lethargy (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Rales (2d - Fatal - **Results in Death**), Rhonchi (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22352 | click or scan EU-EC-10007794566 | | 2021-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Ileus paralytic (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| 22353 | click or scan EU-EC-10007794559 | | 2021-03-04 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Restlessness (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22354 | click or scan EU-EC-10007794501 | | 2021-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| 22355 | click or scan EU-EC-10007794489 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22356 | click or scan EU-EC-10007794202 | | 2021-03-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22357 | click or scan EU-EC-10007794147 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22358 | click or scan EU-EC-10007794123 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22359 | click or scan EU-EC-10007793976 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 22360 | click or scan EU-EC-10007793721 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Axillary pain (2d - Not Recovered/Not Resolved - ), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22361 | click or scan EU-EC-10007793461 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22362 | click or scan EU-EC-10007793219 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22363 | click or scan EU-EC-10007793183 | | 2021-03-04 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory rate decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22364 | click or scan EU-EC-10007793167 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22365 | click or scan EU-EC-10007792884 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (2d - Fatal - **Results in Death**), Cardiac failure (2d - Fatal - **Results in Death**), Cardio-respiratory arrest (2d - Fatal - **Results in Death**), Chest pain (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Pneumonia (2d - Fatal - **Results in Death**), Vomiting (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22366 | click or scan EU-EC-10007792482 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22367 | click or scan EU-EC-10007792282 | | 2021-03-04 | Healthcare Professional | Non EEA | Not Specified | Male | MAGIC syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22368 | click or scan EU-EC-10007791940 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic embolus (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22369 | click or scan EU-EC-10007791414 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22370 | click or scan EU-EC-10007791125 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea at rest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypopnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oral pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22371 | click or scan EU-EC-10007790209 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 22372 | click or scan EU-EC-10007790043 | | 2021-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Hallucination (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22373 | click or scan EU-EC-10007789634 | | 2021-03-04 | Healthcare Professional | EEA | More than 85 Years | Male | Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22374 | click or scan EU-EC-10007789597 | | 2021-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22375 | click or scan EU-EC-10007789065 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (30min - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Fatigue (68h - Unknown - ), Feeling cold (20h - Unknown - ), Hyperhidrosis (20h - Unknown - ), Hypersomnia (68h - Unknown - ), Hypotension (30min - Fatal - **Results in Death**), Illness (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ), Tremor (68h - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22376 | click or scan EU-EC-10007788326 | | 2021-03-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| 22377 | click or scan EU-EC-10007788105 | | 2021-03-04 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination complication (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22378 | click or scan EU-EC-10007787520 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22379 | click or scan EU-EC-10007786022 | | 2021-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 22380 | click or scan EU-EC-10007785938 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22381 | click or scan EU-EC-10007785576 | | 2021-03-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 22382 | click or scan EU-EC-10007785569 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22383 | click or scan EU-EC-10007785500 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Epilepsy (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22384 | click or scan EU-EC-10007784030 | | 2021-03-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cough (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Feeling abnormal (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22385 | click or scan EU-EC-10007784029 | | 2021-03-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22386 | click or scan EU-EC-10007783993 | | 2021-03-04 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22387 | click or scan EU-EC-10007783694 | | 2021-03-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22388 | click or scan EU-EC-10007783671 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Absence of immediate treatment response (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Pulseless electrical activity (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22389 | click or scan EU-EC-10007783605 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22390 | click or scan EU-EC-10007783572 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22391 | click or scan EU-EC-10007783511 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22392 | click or scan EU-EC-10007783507 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22393 | click or scan EU-EC-10007783506 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22394 | click or scan EU-EC-10007783494 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22395 | click or scan EU-EC-10007783467 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22396 | click or scan EU-EC-10007783440 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22397 | click or scan EU-EC-10007783433 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22398 | click or scan EU-EC-10007783370 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22399 | click or scan EU-EC-10007783130 | | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | Bronchial hyperreactivity (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) |
| 22400 | click or scan EU-EC-10007782627 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22401 | click or scan EU-EC-10007782570 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22402 | click or scan EU-EC-10007782547 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22403 | click or scan EU-EC-10007782489 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22404 | click or scan EU-EC-10007782349 | | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Swelling face (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22405 | click or scan EU-EC-10007782297 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22406 | click or scan EU-EC-10007782292 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22407 | click or scan EU-EC-10007782291 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Cough (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22408 | click or scan EU-EC-10007782199 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chills (n/a - Unknown - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Injection site pain (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22409 | click or scan EU-EC-10007782024 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Illness (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22410 | click or scan EU-EC-10007781751 | | 2021-03-03 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gait inability (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22411 | click or scan EU-EC-10007781656 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22412 | click or scan EU-EC-10007781563 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22413 | click or scan EU-EC-10007781362 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden cardiac death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22414 | click or scan EU-EC-10007781118 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypercapnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sinusitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22415 | click or scan EU-EC-10007780816 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Respiratory tract congestion (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22416 | click or scan EU-EC-10007780791 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (3d - Fatal - **Results in Death**, Other Medically Important Condition), Chills (3d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Headache (3d - Fatal - **Results in Death**), Nausea (3d - Fatal - **Results in Death**), Psychomotor hyperactivity (3d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site pain (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22417 | click or scan EU-EC-10007780783 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Atrophy (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral small vessel ischaemic disease (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolic cerebellar infarction (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Embolic cerebral infarction (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22418 | click or scan EU-EC-10007780720 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pulse absent (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22419 | click or scan EU-EC-10007780625 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22420 | click or scan EU-EC-10007780540 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22421 | click or scan EU-EC-10007780529 | | 2021-03-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Non-Hodgkin's lymphoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22422 | click or scan EU-EC-10007780225 | | 2021-03-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ascites (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Omental necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ovarian necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22423 | click or scan EU-EC-10007779817 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atelectasis (5d - Fatal - **Results in Death**), Pleural effusion (5d - Fatal - **Results in Death**), Pulmonary oedema (5d - Fatal - **Results in Death**), Pyrexia (5d - Fatal - **Results in Death**), Respiratory distress (5d - Fatal - **Results in Death**), Sinus tachycardia (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22424 | click or scan EU-EC-10007779616 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22425 | click or scan EU-EC-10007779497 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Mental status changes (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22426 | click or scan EU-EC-10007779455 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22427 | click or scan EU-EC-10007779252 | | 2021-03-03 | Healthcare Professional | Non EEA | Not Specified | Female | Muscle spasms (n/a - Fatal - **Results in Death**), Muscle tightness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22428 | click or scan EU-EC-10007779202 |  | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22429 | click or scan EU-EC-10007778990 |  | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (9d - Fatal - **Results in Death**), Oxygen saturation decreased (9d - Fatal - **Results in Death**), Respiratory distress (9d - Fatal - **Results in Death**), Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - n/a - n/a]) |
| 22430 | click or scan EU-EC-10007778506 |  | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Malaise (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22431 | click or scan EU-EC-10007778500 |  | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (4d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Decreased appetite (4d - Fatal - **Results in Death**), Food refusal (4d - Fatal - **Results in Death**), Memory impairment (4d - Fatal - **Results in Death**), Mobility decreased (4d - Fatal - **Results in Death**), Somnolence (4d - Fatal - **Results in Death**), Visual impairment (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22432 | click or scan EU-EC-10007778372 |  | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22433 | click or scan EU-EC-10007778163 |  | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22434 | click or scan EU-EC-10007777844 |  | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 22435 | click or scan EU-EC-10007777739 |  | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22436 | click or scan EU-EC-10007777709 |  | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22437 | click or scan EU-EC-10007776047 |  | 2021-03-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Chills (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Renal disorder (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22438 | click or scan EU-EC-10007775992 | | 2021-03-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22439 | click or scan EU-EC-10007775623 | | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (3d - Fatal - **Results in Death**), Nervous system disorder (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22440 | click or scan EU-EC-10007775477 | | 2021-03-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22441 | click or scan EU-EC-10007775464 | | 2021-03-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22442 | click or scan EU-EC-10007774522 | | 2021-03-03 | Healthcare Professional | EEA | 18-64 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22443 | click or scan EU-EC-10007773993 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Emphysema (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Left atrial dilatation (n/a - Fatal - **Results in Death**), Lung consolidation (n/a - Fatal - **Results in Death**), Lung opacity (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pulmonary granuloma (n/a - Fatal - **Results in Death**), Pulmonary hilum mass (n/a - Fatal - **Results in Death**), Pulmonary mass (n/a - Fatal - **Results in Death**), Respiratory tract congestion (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22444 | click or scan EU-EC-10007773133 | | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 22445 | click or scan EU-EC-10007772587 | | 2021-03-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cognitive disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22446 | click or scan EU-EC-10007772331 | | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 22447 | click or scan EU-EC-10007772328 | | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22448 | click or scan EU-EC-10007772312 | | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Hypoxia (20min - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22449 | click or scan EU-EC-10007772223 | | 2021-03-03 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22450 | click or scan EU-EC-10007770511 | | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | Coma (n/a - Fatal - **Results in Death**), Diarrhoea (2d - Recovered/Resolved - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22451 | click or scan EU-EC-10007769997 | | 2021-03-03 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 22452 | click or scan EU-EC-10007772013 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22453 | click or scan EU-EC-10007771648 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (1d - Fatal - **Results in Death**), Rheumatoid arthritis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22454 | click or scan EU-EC-10007771618 | | 2021-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Impaired work ability (n/a - Fatal - **Results in Death**, Disabling), Malaise (n/a - Fatal - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22455 | click or scan EU-EC-10007771541 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bedridden (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22456 | click or scan EU-EC-10007771531 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22457 | click or scan EU-EC-10007771521 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22458 | click or scan EU-EC-10007771491 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22459 | click or scan EU-EC-10007771267 | | 2021-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22460 | click or scan EU-EC-10007771251 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22461 | click or scan EU-EC-10007771212 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (7d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Diarrhoea (7d - Fatal - **Results in Death**), Injection site pain (7d - Fatal - **Results in Death**), Vomiting (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22462 | click or scan EU-EC-10007771210 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiogenic shock (1d - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (1d - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22463 | click or scan EU-EC-10007771204 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Neutropenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22464 | click or scan EU-EC-10007771199 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22465 | click or scan EU-EC-10007771037 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haematoma (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 22466 | click or scan EU-EC-10007770862 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22467 | click or scan EU-EC-10007770719 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |
| 22468 | click or scan EU-EC-10007770694 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22469 | click or scan EU-EC-10007770648 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22470 | click or scan EU-EC-10007770521 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22471 | click or scan EU-EC-10007770464 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cyanosis (1d - Fatal - **Results in Death**), Diarrhoea haemorrhagic (1d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Toothache (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22472 | click or scan EU-EC-10007770035 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chronic kidney disease (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**), Septic shock (1d - Fatal - **Results in Death**), Urinary tract infection (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22473 | click or scan EU-EC-10007769621 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22474 | click or scan EU-EC-10007769578 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22475 | click or scan EU-EC-10007769539 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 22476 | click or scan EU-EC-10007769523 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22477 | click or scan EU-EC-10007769344 | | 2021-03-02 | Healthcare Professional | Non EEA | Not Specified | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Diabetic ketoacidosis (5d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22478 | click or scan EU-EC-10007769065 | | 2021-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22479 | click or scan EU-EC-10007769024 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22480 | click or scan EU-EC-10007768949 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22481 | click or scan EU-EC-10007768940 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| 22482 | click or scan EU-EC-10007768816 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Posturing (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22483 | click or scan EU-EC-10007768815 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**), Diarrhoea haemorrhagic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyporesponsive to stimuli (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22484 | click or scan EU-EC-10007768516 | | 2021-03-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**), Chest discomfort (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22485 | click or scan EU-EC-10007768368 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22486 | click or scan EU-EC-10007768245 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22487 | click or scan EU-EC-10007767645 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (14d - Fatal - **Results in Death**), Pneumonia (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22488 | click or scan EU-EC-10007767256 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Staphylococcal sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22489 | click or scan EU-EC-10007766593 | | 2021-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22490 | click or scan EU-EC-10007766581 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Faeces discoloured (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22491 | click or scan EU-EC-10007765739 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22492 | click or scan EU-EC-10007765649 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Body temperature decreased (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22493 | click or scan EU-EC-10007765594 | | 2021-03-02 | Healthcare Professional | EEA | 18-64 Years | Female | Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Intestinal gangrene (n/a - Fatal - **Results in Death**), Visceral venous thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22494 | click or scan EU-EC-10007765505 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22495 | click or scan EU-EC-10007765372 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22496 | click or scan EU-EC-10007764928 | | 2021-03-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haematoma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diabetes insipidus (n/a - Unknown - Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22497 | click or scan EU-EC-10007764414 | | 2021-03-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal wall haematoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Abdominal wall haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22498 | click or scan EU-EC-10007764043 | | 2021-03-02 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22499 | click or scan EU-EC-10007764042 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Respiratory disorder (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22500 | click or scan EU-EC-10007763358 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Diabetes mellitus (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22501 | click or scan EU-EC-10007763350 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Bedridden (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypotonia (n/a - Fatal - **Results in Death**), Irregular breathing (n/a - Fatal - **Results in Death**), Rhonchi (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22502 | click or scan EU-EC-10007763237 | | 2021-03-02 | Healthcare Professional | EEA | 18-64 Years | Female | Arterial thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 22503 | click or scan EU-EC-10007762734 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | Anal incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (3d - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (3d - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 22504 | click or scan EU-EC-10007762217 | | 2021-03-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Illness (n/a - Unknown - ), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22505 | click or scan EU-EC-10007761931 | | 2021-03-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22506 | click or scan EU-EC-10007761831 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 22507 | click or scan EU-EC-10007761417 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22508 | click or scan EU-EC-10007761407 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 22509 | click or scan EU-EC-10007761353 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22510 | click or scan EU-EC-10007761342 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22511 | click or scan EU-EC-10007761334 | | 2021-03-02 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22512 | click or scan EU-EC-10007761030 | | 2021-03-02 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (3d - Fatal - **Results in Death**), Coagulopathy (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22513 | click or scan EU-EC-10007760253 | | 2021-03-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22514 | click or scan EU-EC-10007760010 | | 2021-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (4d - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**), Vomiting projectile (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22515 | click or scan EU-EC-10007759758 | | 2021-03-01 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22516 | click or scan EU-EC-10007759155 | | 2021-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22517 | click or scan EU-EC-10007759011 | | 2021-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22518 | click or scan EU-EC-10007758867 | | 2021-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dyspepsia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (3d - Unknown - ), Feeling abnormal (3d - Unknown - ), Hypophagia (n/a - Unknown - ), Palpitations (n/a - Unknown - ), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Respiratory depression (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22519 | click or scan EU-EC-10007758521 | | 2021-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22520 | click or scan EU-EC-10007756863 | | 2021-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22521 | click or scan EU-EC-10007756435 | | 2021-03-01 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22522 | click or scan EU-EC-10007756340 | | 2021-03-01 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22523 | click or scan EU-EC-10007755439 | | 2021-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (1d - Fatal - **Results in Death**), Respiratory failure (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22524 | click or scan EU-EC-10007755395 | | 2021-03-01 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22525 | click or scan EU-EC-10007755394 | | 2021-03-01 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22526 | click or scan EU-EC-10007755193 | | 2021-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22527 | click or scan EU-EC-10007754939 | | 2021-03-01 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22528 | click or scan EU-EC-10007754892 | | 2021-03-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22529 | click or scan EU-EC-10007754176 | | 2021-03-01 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22530 | click or scan EU-EC-10007750968 | | 2021-03-01 | Healthcare Professional | EEA | 65-85 Years | Male | Oxygen saturation decreased (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 22531 | click or scan EU-EC-10007749406 | | 2021-03-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22532 | click or scan EU-EC-10007749029 | | 2021-03-01 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22533 | click or scan EU-EC-10007748939 | | 2021-03-01 | Healthcare Professional | EEA | More than 85 Years | Female | Bacterial test positive (n/a - Fatal - **Results in Death**), Blood glucose increased (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Muscle twitching (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyelonephritis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22534 | click or scan EU-EC-10007748854 | | 2021-03-01 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22535 | click or scan EU-EC-10007748840 | | 2021-03-01 | Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22536 | click or scan EU-EC-10007746831 | | 2021-03-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dementia Alzheimer's type (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1 d - n/a - Intramuscular]) |
| 22537 | click or scan EU-EC-10007746818 | | 2021-03-01 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22538 | click or scan EU-EC-10007746806 | | 2021-03-01 | Non Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - 1 {DF} - Intramuscular]) |
| 22539 | click or scan EU-EC-10007745999 | | 2021-03-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 22540 | click or scan EU-EC-10007744498 | | 2021-02-28 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - .3mL - Intramuscular]) |
| 22541 | click or scan EU-EC-10007744468 | | 2021-02-28 | Healthcare Professional | EEA | More than 85 Years | Female | Escherichia infection (2d - Fatal - **Results in Death**), Sepsis (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1 d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22542 | click or scan EU-EC-10007744248 |  | 2021-02-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Pyrexia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22543 | click or scan EU-EC-10007743746 |  | 2021-02-28 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22544 | click or scan EU-EC-10007742785 |  | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22545 | click or scan EU-EC-10007742765 |  | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | Status epilepticus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Oral]) |
| 22546 | click or scan EU-EC-10007742670 |  | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22547 | click or scan EU-EC-10007742554 |  | 2021-02-27 | Healthcare Professional | EEA | 18-64 Years | Female | Hyperthermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22548 | click or scan EU-EC-10007742409 |  | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypertension (1d - Recovered/Resolved - **Results in Death**), Hyperthermia (n/a - Not Recovered/Not Resolved - **Results in Death**), Lung disorder (n/a - Not Recovered/Not Resolved - **Results in Death**), Vaccination site inflammation (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22549 | click or scan EU-EC-10007741745 |  | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hemiplegia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22550 | click or scan EU-EC-10007741701 |  | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22551 | click or scan EU-EC-10007741695 |  | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]), [D,L-LYSINE ACETYLSALICYLATE] (S - Cerebrovascular accident prophylaxis - Drug withdrawn - [n/a - 75mg - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22552 | click or scan EU-EC-10007741627 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Recovered/Resolved - **Results in Death**), Tachycardia (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22553 | click or scan EU-EC-10007741614 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | Atrioventricular block complete (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22554 | click or scan EU-EC-10007741600 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22555 | click or scan EU-EC-10007741594 | | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22556 | click or scan EU-EC-10007741528 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | Aplasia (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22557 | click or scan EU-EC-10007741395 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22558 | click or scan EU-EC-10007741378 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 22559 | click or scan EU-EC-10007741311 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22560 | click or scan EU-EC-10007741309 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Lung disorder (n/a - Unknown - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22561 | click or scan EU-EC-10007741270 | | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (5d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22562 | click or scan EU-EC-10007741269 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22563 | click or scan EU-EC-10007741264 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (7d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22564 | click or scan EU-EC-10007741263 | | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (6d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22565 | click or scan EU-EC-10007741259 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22566 | click or scan EU-EC-10007741258 | | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22567 | click or scan EU-EC-10007741252 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (6d - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22568 | click or scan EU-EC-10007741216 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22569 | click or scan EU-EC-10007741090 | | 2021-02-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22570 | click or scan EU-EC-10007741088 | | 2021-02-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22571 | click or scan EU-EC-10007741054 | | 2021-02-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22572 | click or scan EU-EC-10007741045 | | 2021-02-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22573 | click or scan EU-EC-10007741042 | | 2021-02-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22574 | click or scan EU-EC-10007740927 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22575 | click or scan EU-EC-10007740926 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22576 | click or scan EU-EC-10007740753 | | 2021-02-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Choking (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Recovering/Resolving - **Results in Death**), Pyrexia (n/a - Recovering/Resolving - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22577 | click or scan EU-EC-10007740738 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Hypertension (n/a - Not Recovered/Not Resolved - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22578 | click or scan EU-EC-10007740481 | | 2021-02-27 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22579 | click or scan EU-EC-10007740378 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22580 | click or scan EU-EC-10007740366 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22581 | click or scan EU-EC-10007740184 | | 2021-02-27 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22582 | click or scan EU-EC-10007740086 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Coma (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22583 | click or scan EU-EC-10007740078 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Oxygen saturation decreased (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22584 | click or scan EU-EC-10007739812 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22585 | click or scan EU-EC-10007739661 | | 2021-02-27 | Healthcare Professional | EEA | More than 85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**), International normalised ratio increased (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [D,L-LYSINE ACETYLSALICYLATE] (S - Atrial fibrillation - Not applicable - [n/a - 75mg - Oral]), [WARFARIN SODIUM] (S - Atrial fibrillation - Not applicable - [n/a - 1.25 {DF} - Oral]) |
| 22586 | click or scan EU-EC-10007739542 | | 2021-02-27 | Non Healthcare Professional | EEA | More than 85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22587 | click or scan EU-EC-10007739459 | | 2021-02-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22588 | click or scan EU-EC-10007739446 | | 2021-02-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22589 | click or scan EU-EC-10007738815 | | 2021-02-27 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening), Hepatitis E (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22590 | click or scan EU-EC-10007738676 | | 2021-02-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22591 | click or scan EU-EC-10007738548 | | 2021-02-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22592 | click or scan EU-EC-10007738528 | | 2021-02-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22593 | click or scan EU-EC-10007737374 | | 2021-02-27 | Healthcare Professional | Non EEA | Not Specified | Female | Infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22594 | click or scan EU-EC-10007737139 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22595 | click or scan EU-EC-10007736862 | | 2021-02-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22596 | click or scan EU-EC-10007736455 | | 2021-02-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Movement disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Nervous system disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22597 | click or scan EU-EC-10007736335 | | 2021-02-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Hypopnoea (2d - Fatal - **Results in Death**), Palpitations (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22598 | click or scan EU-EC-10007734889 | | 2021-02-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Inflammatory marker increased (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Myelodysplastic syndrome (n/a - Fatal - **Results in Death**), Pancytopenia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22599 | click or scan EU-EC-10007734821 | | 2021-02-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22600 | click or scan EU-EC-10007734750 | | 2021-02-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22601 | click or scan EU-EC-10007734304 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22602 | click or scan EU-EC-10007734290 | | 2021-02-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22603 | click or scan EU-EC-10007733945 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (19d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (19d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (19d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) |
| 22604 | click or scan EU-EC-10007733102 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22605 | click or scan EU-EC-10007732636 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22606 | click or scan EU-EC-10007731386 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (8d - Fatal - **Results in Death**), Cardiovascular disorder (8d - Fatal - **Results in Death**), General physical condition abnormal (8d - Fatal - **Results in Death**), Hyperpyrexia (0d - Fatal - **Results in Death**), Jaundice (0d - Fatal - **Results in Death**), Myocarditis septic (0d - Fatal - **Results in Death**), Nasopharyngitis (8d - Fatal - **Results in Death**), Pain in extremity (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22607 | click or scan EU-EC-10007730862 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 22608 | click or scan EU-EC-10007730762 | | 2021-02-26 | Healthcare Professional | Non EEA | Not Specified | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22609 | click or scan EU-EC-10007730212 | | 2021-02-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Epistaxis (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22610 | click or scan EU-EC-10007730003 | | 2021-02-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin ulcer (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22611 | click or scan EU-EC-10007729856 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22612 | click or scan EU-EC-10007729845 | | 2021-02-26 | Non Healthcare Professional | EEA | More than 85 Years | Male | Dysphagia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22613 | click or scan EU-EC-10007729820 | | 2021-02-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypophagia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22614 | click or scan EU-EC-10007729813 | | 2021-02-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22615 | click or scan EU-EC-10007729795 | | 2021-02-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22616 | click or scan EU-EC-10007729792 | | 2021-02-26 | Non Healthcare Professional | EEA | More than 85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22617 | click or scan EU-EC-10007727398 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22618 | click or scan EU-EC-10007727370 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22619 | click or scan EU-EC-10007727369 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22620 | click or scan EU-EC-10007727291 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22621 | click or scan EU-EC-10007727273 | | 2021-02-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22622 | click or scan EU-EC-10007726557 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Crepitations (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Productive cough (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22623 | click or scan EU-EC-10007726472 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22624 | click or scan EU-EC-10007726397 | | 2021-02-25 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR]) |
| 22625 | click or scan EU-EC-10007726058 | | 2021-02-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22626 | click or scan EU-EC-10007725846 | | 2021-02-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (6d - Recovered/Resolved - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22627 | click or scan EU-EC-10007725730 | | 2021-02-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22628 | click or scan EU-EC-10007725729 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Confusional state (n/a - Unknown - ), Hypertension (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22629 | click or scan EU-EC-10007725693 | | 2021-02-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22630 | click or scan EU-EC-10007723549 | | 2021-02-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**), Myalgia (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22631 | click or scan EU-EC-10007723172 | | 2021-02-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22632 | click or scan EU-EC-10007723054 | | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22633 | click or scan EU-EC-10007723042 | | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22634 | click or scan EU-EC-10007722492 |  | 2021-02-25 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22635 | click or scan EU-EC-10007722257 |  | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22636 | click or scan EU-EC-10007722134 |  | 2021-02-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22637 | click or scan EU-EC-10007722038 |  | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22638 | click or scan EU-EC-10007721239 |  | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22639 | click or scan EU-EC-10007721221 |  | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening), Injected limb mobility decreased (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22640 | click or scan EU-EC-10007721191 |  | 2021-02-25 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22641 | click or scan EU-EC-10007720964 |  | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22642 | click or scan EU-EC-10007720134 |  | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22643 | click or scan EU-EC-10007720090 |  | 2021-02-25 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22644 | click or scan EU-EC-10007720021 |  | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | Back pain (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Hypertension (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22645 | click or scan EU-EC-10007719978 | | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22646 | click or scan EU-EC-10007718860 | | 2021-02-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) |
| 22647 | click or scan EU-EC-10007718598 | | 2021-02-25 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure increased (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Ischaemic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22648 | click or scan EU-EC-10007718594 | | 2021-02-25 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22649 | click or scan EU-EC-10007718525 | | 2021-02-25 | Healthcare Professional | EEA | Not Specified | Male | Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22650 | click or scan EU-EC-10007718243 | | 2021-02-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22651 | click or scan EU-EC-10007716198 | | 2021-02-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Memory impairment (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22652 | click or scan EU-EC-10007715940 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22653 | click or scan EU-EC-10007715930 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Head injury (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory disorder (12d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22654 | click or scan EU-EC-10007715927 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory failure (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22655** | click or scan EU-EC-10007715917 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22656** | click or scan EU-EC-10007715915 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **22657** | click or scan EU-EC-10007715906 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **22658** | click or scan EU-EC-10007715902 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **22659** | click or scan EU-EC-10007715481 | | 2021-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22660** | click or scan EU-EC-10007715472 | | 2021-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22661** | click or scan EU-EC-10007715463 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| **22662** | click or scan EU-EC-10007714988 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (2d - Fatal - **Results in Death**), Seizure (2d - Fatal - **Results in Death**), Unresponsive to stimuli (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22663** | click or scan EU-EC-10007714975 | | 2021-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **22664** | click or scan EU-EC-10007714808 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden cardiac death (1d - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22665** | click or scan EU-EC-10007714677 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22666 | click or scan EU-EC-10007714553 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22667 | click or scan EU-EC-10007714512 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (1d - Fatal - **Results in Death**), Dementia (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22668 | click or scan EU-EC-10007714432 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22669 | click or scan EU-EC-10007714401 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Feeling abnormal (1d - Fatal - **Results in Death**), Palpitations (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22670 | click or scan EU-EC-10007714394 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (1d - Fatal - **Results in Death**), COVID-19 (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22671 | click or scan EU-EC-10007714078 | | 2021-02-24 | Healthcare Professional | Non EEA | Not Specified | Male | Arthralgia (n/a - Unknown - Other Medically Important Condition), Cardiogenic shock (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22672 | click or scan EU-EC-10007714048 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | General physical health deterioration (2d - Fatal - **Results in Death**), Hypotension (2d - Fatal - **Results in Death**), Lethargy (2d - Fatal - **Results in Death**), Mental status changes (2d - Fatal - **Results in Death**), Respiratory distress (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22673 | click or scan EU-EC-10007713997 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22674 | click or scan EU-EC-10007713915 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (8d - Fatal - **Results in Death**), Communication disorder (n/a - Fatal - **Results in Death**), Confusional state (8d - Fatal - **Results in Death**), Feeding disorder (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22675 | click or scan EU-EC-10007713849 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dysarthria (2d - Fatal - **Results in Death**), Fatigue (3d - Fatal - **Results in Death**), Malaise (3d - Fatal - **Results in Death**), Memory impairment (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22676** | click or scan EU-EC-10007713749 |  | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22677** | click or scan EU-EC-10007713710 |  | 2021-02-24 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Asthenia (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **22678** | click or scan EU-EC-10007713589 |  | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (3d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Hyperaesthesia (3d - Fatal - **Results in Death**), Mental status changes (3d - Fatal - **Results in Death**), Oxygen saturation decreased (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Screaming (n/a - Fatal - **Results in Death**), Speech disorder (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22679** | click or scan EU-EC-10007713584 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Cardiovascular event prophylaxis - Drug withdrawn - [n/a - 1 {DF} - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (S - Hypertension - Drug withdrawn - [n/a - 1 {DF} - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Dyslipidaemia - Drug withdrawn - [n/a - 1 {DF} - Oral]), [COLECALCIFEROL] (S - Prophylaxis - Unknown - [n/a - n/a - Oral]), [RAMIPRIL] (S - Hypertension - Drug withdrawn - [n/a - 1 {DF} - Oral]) |
| **22680** | click or scan EU-EC-10007713531 |  | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **22681** | click or scan EU-EC-10007713518 |  | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Injection site pain (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22682** | click or scan EU-EC-10007713371 |  | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory distress (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical condition abnormal (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **22683** | click or scan EU-EC-10007713049 |  | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22684 | click or scan EU-EC-10007712902 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22685 | click or scan EU-EC-10007712900 | | 2021-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22686 | click or scan EU-EC-10007712369 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22687 | click or scan EU-EC-10007712368 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22688 | click or scan EU-EC-10007712294 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22689 | click or scan EU-EC-10007711855 | | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 22690 | click or scan EU-EC-10007711838 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 22691 | click or scan EU-EC-10007711478 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 22692 | click or scan EU-EC-10007711474 | | 2021-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22693 | click or scan EU-EC-10007711469 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22694** | click or scan EU-EC-10007711408 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **22695** | click or scan EU-EC-10007711149 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bradycardia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **22696** | click or scan EU-EC-10007710733 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | C-reactive protein increased (7d - Fatal - **Results in Death**), Secretion discharge (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| **22697** | click or scan EU-EC-10007710648 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **22698** | click or scan EU-EC-10007710634 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Fatigue (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**), Hypoaesthesia (2d - Fatal - **Results in Death**), Pain in extremity (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22699** | click or scan EU-EC-10007710618 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22700** | click or scan EU-EC-10007710551 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| **22701** | click or scan EU-EC-10007710468 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22702** | click or scan EU-EC-10007710391 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Epistaxis (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22703** | click or scan EU-EC-10007710096 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22704** | click or scan EU-EC-10007709981 |  | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **22705** | click or scan EU-EC-10007709800 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| **22706** | click or scan EU-EC-10007709494 |  | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **22707** | click or scan EU-EC-10007709493 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **22708** | click or scan EU-EC-10007709427 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **22709** | click or scan EU-EC-10007709426 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | General physical condition abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22710** | click or scan EU-EC-10007709425 |  | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **22711** | click or scan EU-EC-10007709323 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| **22712** | click or scan EU-EC-10007709317 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| **22713** | click or scan EU-EC-10007709311 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| **22714** | click or scan EU-EC-10007708780 |  | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22715 | click or scan EU-EC-10007708779 | | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22716 | click or scan EU-EC-10007708715 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22717 | click or scan EU-EC-10007708562 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22718 | click or scan EU-EC-10007708490 | | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 22719 | click or scan EU-EC-10007708475 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mitral valve incompetence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 22720 | click or scan EU-EC-10007707211 | | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22721 | click or scan EU-EC-10007706971 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22722 | click or scan EU-EC-10007706926 | | 2021-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - ), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22723 | click or scan EU-EC-10007706851 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22724 | click or scan EU-EC-10007706796 | | 2021-02-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22725** | click or scan EU-EC-10007706729 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22726** | click or scan EU-EC-10007706487 | | 2021-02-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **22727** | click or scan EU-EC-10007706344 | | 2021-02-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22728** | click or scan EU-EC-10007706343 | | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22729** | click or scan EU-EC-10007706284 | | 2021-02-24 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (15d - Fatal - **Results in Death**), Pyrexia (15d - Fatal - **Results in Death**), Upper respiratory tract infection (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22730** | click or scan EU-EC-10007706282 | | 2021-02-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Red blood cell sedimentation rate increased (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **22731** | click or scan EU-EC-10007706280 | | 2021-02-24 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **22732** | click or scan EU-EC-10007705388 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Unknown - ), Myocardial infarction (1d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **22733** | click or scan EU-EC-10007705292 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22734** | click or scan EU-EC-10007705192 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22735 | click or scan EU-EC-10007705188 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22736 | click or scan EU-EC-10007705186 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (22d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22737 | click or scan EU-EC-10007705165 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Epistaxis (2d - Fatal - **Results in Death**), Eye haemorrhage (2d - Fatal - **Results in Death**), Mouth haemorrhage (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Staring (2d - Fatal - **Results in Death**), Tremor (2d - Fatal - **Results in Death**), Unresponsive to stimuli (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22738 | click or scan EU-EC-10007705151 | | 2021-02-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22739 | click or scan EU-EC-10007704861 | | 2021-02-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22740 | click or scan EU-EC-10007702642 | | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22741 | click or scan EU-EC-10007701840 | | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22742 | click or scan EU-EC-10007701765 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22743 | click or scan EU-EC-10007701757 | | 2021-02-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Brain hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22744 | click or scan EU-EC-10007701651 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22745 | click or scan EU-EC-10007701596 | | 2021-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Muscle rigidity (7d - Fatal - **Results in Death**), Pyrexia (7d - Fatal - **Results in Death**), Urinary tract infection (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22746 | click or scan EU-EC-10007701565 | | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22747 | click or scan EU-EC-10007701517 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22748 | click or scan EU-EC-10007701512 | | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22749 | click or scan EU-EC-10007701494 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22750 | click or scan EU-EC-10007701488 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Back pain (2d - Fatal - **Results in Death**), Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Neck pain (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Seizure like phenomena (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22751 | click or scan EU-EC-10007701446 | | 2021-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22752 | click or scan EU-EC-10007700952 | | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22753 | click or scan EU-EC-10007700922 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22754 | click or scan EU-EC-10007700853 | | 2021-02-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Atelectasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22755 | click or scan EU-EC-10007700537 | | 2021-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22756** | click or scan EU-EC-10007700282 |  | 2021-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22757** | click or scan EU-EC-10007700182 |  | 2021-02-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22758** | click or scan EU-EC-10007700146 |  | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Livedo reticularis (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22759** | click or scan EU-EC-10007699764 |  | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (4d - Fatal - **Results in Death**), Chest discomfort (4d - Fatal - **Results in Death**), Dyspnoea (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22760** | click or scan EU-EC-10007699430 |  | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **22761** | click or scan EU-EC-10007698153 |  | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22762** | click or scan EU-EC-10007698050 |  | 2021-02-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **22763** | click or scan EU-EC-10007697843 |  | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Cyanosis (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22764** | click or scan EU-EC-10007697512 |  | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **22765** | click or scan EU-EC-10007697435 |  | 2021-02-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22766** | click or scan EU-EC-10007697379 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22767** | click or scan EU-EC-10007697263 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **22768** | click or scan EU-EC-10007697106 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Electrolyte imbalance (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22769** | click or scan EU-EC-10007696925 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (1mo - Fatal - **Results in Death**), General physical health deterioration (13d - Fatal - **Results in Death**), Lethargy (13d - Fatal - **Results in Death**), Pneumonia (1mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **22770** | click or scan EU-EC-10007696780 | | 2021-02-23 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **22771** | click or scan EU-EC-10007696437 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **22772** | click or scan EU-EC-10007696434 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**), Tachycardia (1d - Fatal - **Results in Death**), Tachypnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **22773** | click or scan EU-EC-10007696039 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **22774** | click or scan EU-EC-10007695108 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **22775** | click or scan EU-EC-10007694613 | | 2021-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22776** | click or scan EU-EC-10007694081 | | 2021-02-23 | Non Healthcare Professional | EEA | 65-85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22777** | click or scan EU-EC-10007694075 | | 2021-02-23 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22778** | click or scan EU-EC-10007694008 | | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **22779** | click or scan EU-EC-10007693877 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **22780** | click or scan EU-EC-10007693875 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic valve stenosis (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **22781** | click or scan EU-EC-10007693777 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **22782** | click or scan EU-EC-10007693772 | | 2021-02-23 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **22783** | click or scan EU-EC-10007693624 | | 2021-02-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ), Weight decreased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **22784** | click or scan EU-EC-10007693560 | | 2021-02-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspepsia (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **22785** | click or scan EU-EC-10007693368 | | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22786 | click or scan EU-EC-10007693297 |  | 2021-02-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (13d - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22787 | click or scan EU-EC-10007691674 |  | 2021-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (5d - Fatal - **Results in Death**), Chest pain (5d - Fatal - **Results in Death**), Cold sweat (5d - Fatal - **Results in Death**), Hypotension (5d - Fatal - **Results in Death**), Pallor (5d - Fatal - **Results in Death**), Pulmonary embolism (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22788 | click or scan EU-EC-10007691660 |  | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Balance disorder (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subdural haematoma (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22789 | click or scan EU-EC-10007691417 |  | 2021-02-22 | Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22790 | click or scan EU-EC-10007691235 |  | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asymptomatic COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22791 | click or scan EU-EC-10007691230 |  | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22792 | click or scan EU-EC-10007691119 |  | 2021-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22793 | click or scan EU-EC-10007691006 |  | 2021-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22794 | click or scan EU-EC-10007690953 |  | 2021-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22795 | click or scan EU-EC-10007690643 |  | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Posture abnormal (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22796 | click or scan EU-EC-10007690391 | | 2021-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22797 | click or scan EU-EC-10007690294 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Female | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22798 | click or scan EU-EC-10007690292 | | 2021-02-22 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | APIXABAN 5MG TABLET (S - Atrial flutter - Unknown - [n/a - 1 {DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22799 | click or scan EU-EC-10007690152 | | 2021-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (13d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22800 | click or scan EU-EC-10007690151 | | 2021-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22801 | click or scan EU-EC-10007689975 | | 2021-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22802 | click or scan EU-EC-10007689845 | | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| 22803 | click or scan EU-EC-10007689504 | | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Coma (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Disturbance in attention (n/a - Fatal - **Results in Death**), Peripheral vascular disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22804 | click or scan EU-EC-10007689373 | | 2021-02-22 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22805 | click or scan EU-EC-10007689270 | | 2021-02-22 | Healthcare Professional | Non EEA | 65-85 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22806 | click or scan EU-EC-10007688255 | | 2021-02-22 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22807 | click or scan EU-EC-10007687861 | | 2021-02-22 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22808 | click or scan EU-EC-10007687682 | | 2021-02-22 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Sepsis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22809 | click or scan EU-EC-10007687672 | | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Recovered/Resolved - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hallucination (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myoclonus (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22810 | click or scan EU-EC-10007687635 | | 2021-02-22 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22811 | click or scan EU-EC-10007686964 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Bradyarrhythmia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Hypotonic-hyporesponsive episode (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 22812 | click or scan EU-EC-10007686436 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22813 | click or scan EU-EC-10007685843 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22814 | click or scan EU-EC-10007685708 | | 2021-02-22 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22815 | click or scan EU-EC-10007685320 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Female | Nasopharyngitis (6d - Fatal - **Results in Death**), Upper respiratory tract infection (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22816 | click or scan EU-EC-10007684362 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22817** | click or scan EU-EC-10007683526 | | 2021-02-22 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Sepsis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22818** | click or scan EU-EC-10007683100 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **22819** | click or scan EU-EC-10007681560 | | 2021-02-22 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **22820** | click or scan EU-EC-10007681302 | | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cognitive disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **22821** | click or scan EU-EC-10007681156 | | 2021-02-22 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cyanosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Hypotension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **22822** | click or scan EU-EC-10007680764 | | 2021-02-21 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **22823** | click or scan EU-EC-10007679410 | | 2021-02-20 | Healthcare Professional | EEA | 18-64 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22824** | click or scan EU-EC-10007678930 | | 2021-02-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **22825** | click or scan EU-EC-10007678758 | | 2021-02-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22826** | click or scan EU-EC-10007678489 |  | 2021-02-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Diabetic ketoacidosis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Hyperglycaemia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Malaise (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **22827** | click or scan EU-EC-10007677877 |  | 2021-02-20 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22828** | click or scan EU-EC-10007677806 |  | 2021-02-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **22829** | click or scan EU-EC-10007677789 |  | 2021-02-20 | Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Recovering/Resolving - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22830** | click or scan EU-EC-10007677580 |  | 2021-02-20 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **22831** | click or scan EU-EC-10007677575 |  | 2021-02-20 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Tooth abscess (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **22832** | click or scan EU-EC-10007677568 |  | 2021-02-20 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Coronavirus infection (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22833** | click or scan EU-EC-10007677567 |  | 2021-02-20 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22834** | click or scan EU-EC-10007677562 |  | 2021-02-20 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Coronavirus infection (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22835** | click or scan EU-EC-10007677558 |  | 2021-02-20 | Non Healthcare Professional | EEA | More than 85 Years | Not Specified | Coronavirus infection (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Unknown - ), SARS-CoV-2 test positive (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **22836** | click or scan EU-EC-10007677384 |  | 2021-02-20 | Healthcare Professional | EEA | 65-85 Years | Male | Road traffic accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22837** | click or scan EU-EC-10007677322 | | 2021-02-20 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22838** | click or scan EU-EC-10007677265 | | 2021-02-20 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **22839** | click or scan EU-EC-10007677199 | | 2021-02-20 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22840** | click or scan EU-EC-10007677192 | | 2021-02-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22841** | click or scan EU-EC-10007676917 | | 2021-02-20 | Healthcare Professional | EEA | 65-85 Years | Male | Jaundice (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **22842** | click or scan EU-EC-10007676898 | | 2021-02-20 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (3d - Fatal - **Results in Death**), Circulatory collapse (3d - Fatal - **Results in Death**), Hyperpyrexia (3d - Fatal - **Results in Death**), Vaccination complication (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |
| **22843** | click or scan EU-EC-10007675025 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **22844** | click or scan EU-EC-10007673855 | | 2021-02-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Immobile (4d - Fatal - **Results in Death**, Other Medically Important Condition), Pruritus (8d - Fatal - **Results in Death**), Respiratory disorder (3d - Fatal - **Results in Death**), Unresponsive to stimuli (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22845** | click or scan EU-EC-10007671538 | | 2021-02-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **22846** | click or scan EU-EC-10007670320 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **22847** | click or scan EU-EC-10007669361 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22848 | click or scan EU-EC-10007669325 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22849 | click or scan EU-EC-10007669247 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22850 | click or scan EU-EC-10007669170 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22851 | click or scan EU-EC-10007669096 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22852 | click or scan EU-EC-10007669068 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22853 | click or scan EU-EC-10007669009 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22854 | click or scan EU-EC-10007668628 | | 2021-02-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22855 | click or scan EU-EC-10007668519 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22856 | click or scan EU-EC-10007668458 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22857 | click or scan EU-EC-10007668406 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22858** | click or scan EU-EC-10007668383 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22859** | click or scan EU-EC-10007668369 | | 2021-02-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **22860** | click or scan EU-EC-10007668316 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22861** | click or scan EU-EC-10007667553 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22862** | click or scan EU-EC-10007667405 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22863** | click or scan EU-EC-10007667294 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22864** | click or scan EU-EC-10007666983 | | 2021-02-19 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22865** | click or scan EU-EC-10007666828 | | 2021-02-19 | Healthcare Professional | EEA | 18-64 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **22866** | click or scan EU-EC-10007666274 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **22867** | click or scan EU-EC-10007666273 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22868 | click or scan EU-EC-10007666223 |  | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pancreatitis acute (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Personality change (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (4d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22869 | click or scan EU-EC-10007666201 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [23d - n/a - Intramuscular]) |
| 22870 | click or scan EU-EC-10007666171 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22871 | click or scan EU-EC-10007665991 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (0d - Fatal - **Results in Death**), Respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22872 | click or scan EU-EC-10007665353 |  | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22873 | click or scan EU-EC-10007665215 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22874 | click or scan EU-EC-10007665187 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22875 | click or scan EU-EC-10007665151 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22876 | click or scan EU-EC-10007665048 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22877 | click or scan EU-EC-10007665017 |  | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **22878** | click or scan EU-EC-10007665013 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Hypotension (1h - Recovered/Resolved - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **22879** | click or scan EU-EC-10007664883 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Rectal haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **22880** | click or scan EU-EC-10007664863 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **22881** | click or scan EU-EC-10007664853 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary oedema (1d - Fatal - **Results in Death**), Tachycardia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22882** | click or scan EU-EC-10007664843 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhagic stroke (3d - Fatal - **Results in Death**), Hypertension (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **22883** | click or scan EU-EC-10007664712 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **22884** | click or scan EU-EC-10007664355 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), [OXAZEPAM] (S - Anxiety - Not applicable - [n/a - 10mg - Oral]) |
| **22885** | click or scan EU-EC-10007664283 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Nausea (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Pain - Drug withdrawn - [n/a - 5mg - n/a]) |
| **22886** | click or scan EU-EC-10007664252 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening), Injection site erythema (5d - Recovered/Resolved - ), Injection site inflammation (5d - Recovered/Resolved - ), Injection site swelling (5d - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22887 | click or scan EU-EC-10007664248 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22888 | click or scan EU-EC-10007664237 | | 2021-02-19 | Healthcare Professional | EEA | Not Specified | Female | Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22889 | click or scan EU-EC-10007664199 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22890 | click or scan EU-EC-10007663965 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 22891 | click or scan EU-EC-10007663811 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Male | Hyperthermia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22892 | click or scan EU-EC-10007663762 | | 2021-02-19 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22893 | click or scan EU-EC-10007663756 | | 2021-02-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22894 | click or scan EU-EC-10007660971 | | 2021-02-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (8d - Fatal - **Results in Death**), Drug ineffective (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 22895 | click or scan EU-EC-10007660858 | | 2021-02-18 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (3d - Fatal - **Results in Death**), Oxygen saturation decreased (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 22896 | click or scan EU-EC-10007660769 | | 2021-02-18 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]), [RISPERIDONE] (S - Psychotic disorder - Not applicable - [6d - .5mg - Oral]), [RISPERIDONE] (S - Psychotic disorder - Not applicable - [n/a - 1mg - Oral]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22897 | click or scan EU-EC-10007660689 | | 2021-02-18 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory distress syndrome (1d - Fatal - **Results in Death**), Depressed level of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 22898 | click or scan EU-EC-10007657717 | | 2021-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening), Sudden death (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22899 | click or scan EU-EC-10007655976 | | 2021-02-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22900 | click or scan EU-EC-10007655887 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 22901 | click or scan EU-EC-10007655569 | | 2021-02-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Body temperature abnormal (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Feeling abnormal (3d - Fatal - **Results in Death**), Limb discomfort (3d - Fatal - **Results in Death**), Swelling (2d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 22902 | click or scan EU-EC-10007653727 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22903 | click or scan EU-EC-10007653585 | | 2021-02-18 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22904 | click or scan EU-EC-10007652574 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Female | Acidosis (1d - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (1d - Fatal - **Results in Death**), Cor pulmonale (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Hyperkalaemia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22905 | click or scan EU-EC-10007652238 | | 2021-02-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [1d - n/a - Intramuscular]) |
| 22906 | click or scan EU-EC-10007652042 | | 2021-02-18 | Healthcare Professional | EEA | More than 85 Years | Female | Agitation (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Sedation (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22907 | click or scan EU-EC-10007651961 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22908 | click or scan EU-EC-10007651931 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22909 | click or scan EU-EC-10007651717 | | 2021-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22910 | click or scan EU-EC-10007651569 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (0d - Fatal - **Results in Death**), General physical health deterioration (0d - Fatal - **Results in Death**), Oxygen saturation decreased (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**), Respiratory disorder (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22911 | click or scan EU-EC-10007651464 | | 2021-02-18 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22912 | click or scan EU-EC-10007651431 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22913 | click or scan EU-EC-10007651364 | | 2021-02-18 | Healthcare Professional | Non EEA | Not Specified | Male | Confusional state (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22914 | click or scan EU-EC-10007650719 | | 2021-02-18 | Healthcare Professional | EEA | Not Specified | Female | Basilar artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22915 | click or scan EU-EC-10007650704 | | 2021-02-18 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Syncope (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [FENTANYL] (S - Pain - Dose not changed - [n/a - 1 {DF} - n/a]) |
| 22916 | click or scan EU-EC-10007650378 | | 2021-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22917 | click or scan EU-EC-10007648546 | | 2021-02-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22918 | click or scan EU-EC-10007648203 | | 2021-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 22919 | click or scan EU-EC-10007648137 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (3d - Fatal - **Results in Death**), Fall (3d - Fatal - **Results in Death**), Pyrexia (3d - Fatal - **Results in Death**), Skin warm (3d - Fatal - **Results in Death**), Unresponsive to stimuli (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22920 | click or scan EU-EC-10007648131 | | 2021-02-17 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Completed suicide (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22921 | click or scan EU-EC-10007647975 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22922 | click or scan EU-EC-10007647880 | | 2021-02-17 | Healthcare Professional | EEA | 18-64 Years | Male | Haemophagocytic lymphohistiocytosis (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatitis acute (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), TOCILIZUMAB [TOCILIZUMAB] (S - COVID-19 pneumonia - Not applicable - [n/a - n/a - n/a]), [AMOXICILLIN SODIUM, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID] (S - n/a - Not applicable - [n/a - 1 {DF} - Oral]), [DEXKETOPROFEN, DEXKETOPROFEN TROMETAMOL] (S - n/a - Not applicable - [1d - n/a - n/a]), [METAMIZOLE MAGNESIUM] (S - n/a - Not applicable - [1d - n/a - n/a]), [METAMIZOLE MAGNESIUM] (S - n/a - Not applicable - [n/a - 1 {DF} - Oral]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISUCCINATE] (S - n/a - Not applicable - [1d - n/a - n/a]), [NOT AVAILABLE] (S - n/a - Not applicable - [n/a - 1g - Oral]), [NOT AVAILABLE] (S - n/a - Not applicable - [n/a - 30mg - Oral]), [PARACETAMOL] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| 22923 | click or scan EU-EC-10007647809 | | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Hepatitis acute (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR]) |
| 22924 | click or scan EU-EC-10007647721 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Prerenal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22925 | click or scan EU-EC-10007647570 | | 2021-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [24d - 1 {DF} - Intramuscular]) |
| 22926 | click or scan EU-EC-10007647552 | | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22927 | click or scan EU-EC-10007647526 | | 2021-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22928 | click or scan EU-EC-10007647401 | | 2021-02-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22929 | click or scan EU-EC-10007647279 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22930 | click or scan EU-EC-10007647256 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 22931 | click or scan EU-EC-10007645930 | | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22932 | click or scan EU-EC-10007645637 | | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Emphysema (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 22933 | click or scan EU-EC-10007644716 | | 2021-02-17 | Healthcare Professional | EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22934 | click or scan EU-EC-10007644467 | | 2021-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Decreased appetite (2d - Fatal - **Results in Death**), Depressed level of consciousness (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22935 | click or scan EU-EC-10007644232 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 22936 | click or scan EU-EC-10007644194 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22937 | click or scan EU-EC-10007643445 | | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22938 | click or scan EU-EC-10007643387 | | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22939 | click or scan EU-EC-10007643276 | | 2021-02-17 | Healthcare Professional | Non EEA | Not Specified | Female | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22940 | click or scan EU-EC-10007643111 | | 2021-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22941 | click or scan EU-EC-10007642858 | | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (1d - Fatal - **Results in Death**), Back pain (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22942 | click or scan EU-EC-10007642441 | | 2021-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22943 | click or scan EU-EC-10007641345 | | 2021-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dermatitis allergic (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22944 | click or scan EU-EC-10007640674 | | 2021-02-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22945 | click or scan EU-EC-10007640550 | | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic cerebral infarction (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22946 | click or scan EU-EC-10007640471 |  | 2021-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 22947 | click or scan EU-EC-10007640440 |  | 2021-02-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Chest X-ray abnormal (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22948 | click or scan EU-EC-10007640164 |  | 2021-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 22949 | click or scan EU-EC-10007640089 |  | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22950 | click or scan EU-EC-10007640081 |  | 2021-02-17 | Healthcare Professional | EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 22951 | click or scan EU-EC-10007639836 |  | 2021-02-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Confusional state (n/a - Unknown - ), Illness (n/a - Unknown - ), Migraine (n/a - Unknown - ), Muscle fatigue (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22952 | click or scan EU-EC-10007639674 |  | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 22953 | click or scan EU-EC-10007639530 |  | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22954 | click or scan EU-EC-10007639519 |  | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (4d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 22955 | click or scan EU-EC-10007639513 |  | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ileus paralytic (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Microcytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 22956 | click or scan EU-EC-10007639370 |  | 2021-02-17 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22957 | click or scan EU-EC-10007639044 |  | 2021-02-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 22958 | click or scan EU-EC-10007638966 |  | 2021-02-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22959 | click or scan EU-EC-10007638483 |  | 2021-02-17 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22960 | click or scan EU-EC-10007637963 |  | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 22961 | click or scan EU-EC-10007637853 |  | 2021-02-17 | Healthcare Professional | EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 22962 | click or scan EU-EC-10007635483 |  | 2021-02-17 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22963 | click or scan EU-EC-10007635568 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22964 | click or scan EU-EC-10007635516 |  | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 22965 | click or scan EU-EC-10007635492 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22966 | click or scan EU-EC-10007635421 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Basal ganglia stroke (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22967 | click or scan EU-EC-10007635302 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), General physical health deterioration (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 22968 | click or scan EU-EC-10007635246 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22969 | click or scan EU-EC-10007635198 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (8d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22970 | click or scan EU-EC-10007635150 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (5d - Fatal - **Results in Death**), Rash (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22971 | click or scan EU-EC-10007635069 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22972 | click or scan EU-EC-10007635067 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22973 | click or scan EU-EC-10007635055 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Body temperature increased (2d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**), Lethargy (2d - Fatal - **Results in Death**), Neck pain (2d - Fatal - **Results in Death**), Respiration abnormal (5min - Fatal - **Results in Death**), Tremor (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22974 | click or scan EU-EC-10007634916 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cold sweat (1d - Fatal - **Results in Death**), Crepitations (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Pallor (1d - Fatal - **Results in Death**), Productive cough (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 2 {DF} - Intramuscular]) |
| 22975 | click or scan EU-EC-10007634912 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (8d - Fatal - **Results in Death**), Chest pain (8d - Fatal - **Results in Death**), Confusional state (8d - Fatal - **Results in Death**), Decreased appetite (8d - Fatal - **Results in Death**), Headache (8d - Fatal - **Results in Death**), Hepatic enzyme increased (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22976 | click or scan EU-EC-10007634817 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aneurysm ruptured (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22977 | click or scan EU-EC-10007634623 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Nausea (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22978 | click or scan EU-EC-10007634481 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22979 | click or scan EU-EC-10007634282 | | 2021-02-16 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1 {DF} - Intramuscular]) |
| 22980 | click or scan EU-EC-10007634279 | | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22981 | click or scan EU-EC-10007634225 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (5d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22982 | click or scan EU-EC-10007634142 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22983 | click or scan EU-EC-10007633973 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (5d - Fatal - **Results in Death**), Oedema (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22984 | click or scan EU-EC-10007633838 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - Disabling), Death (n/a - Fatal - **Results in Death**, Disabling), Illness (n/a - Recovering/Resolving - Disabling), Migraine (n/a - Recovered/Resolved - Disabling), Nervousness (n/a - Recovered/Resolved - Disabling), Pain (n/a - Unknown - Disabling), Pruritus (n/a - Recovered/Resolved - Disabling), Pyrexia (n/a - Recovered/Resolved - Disabling), Swelling (n/a - Unknown - Disabling), Tremor (n/a - Unknown - Disabling), Vomiting (n/a - Unknown - Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 22985 | click or scan EU-EC-10007633814 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22986 | click or scan EU-EC-10007633569 | | 2021-02-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Balance disorder (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**), Faeces discoloured (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 22987 | click or scan EU-EC-10007633545 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 22988 | click or scan EU-EC-10007633225 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| 22989 | click or scan EU-EC-10007632780 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22990 | click or scan EU-EC-10007632779 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22991 | click or scan EU-EC-10007632573 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (2d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Feeling abnormal (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 22992 | click or scan EU-EC-10007632449 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22993 | click or scan EU-EC-10007632323 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Body temperature increased (1d - Fatal - **Results in Death**), Complication associated with device (1d - Fatal - **Results in Death**), Cough (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**), Secretion discharge (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22994 | click or scan EU-EC-10007632252 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asymptomatic COVID-19 (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22995 | click or scan EU-EC-10007632101 | | 2021-02-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 22996 | click or scan EU-EC-10007632085 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **22997** | click or scan EU-EC-10007631944 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22998** | click or scan EU-EC-10007631775 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (22d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **22999** | click or scan EU-EC-10007631700 |  | 2021-02-16 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23000** | click or scan EU-EC-10007631665 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (6d - Fatal - **Results in Death**), General physical health deterioration (6d - Fatal - **Results in Death**), Hypophagia (6d - Fatal - **Results in Death**), Hyporesponsive to stimuli (6d - Fatal - **Results in Death**), Somnolence (6d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23001** | click or scan EU-EC-10007631664 |  | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23002** | click or scan EU-EC-10007631557 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23003** | click or scan EU-EC-10007631424 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23004** | click or scan EU-EC-10007631388 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23005** | click or scan EU-EC-10007631387 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23006** | click or scan EU-EC-10007631279 |  | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23007** | click or scan EU-EC-10007631225 |  | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23008 | click or scan EU-EC-10007631210 |  | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23009 | click or scan EU-EC-10007630961 |  | 2021-02-16 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23010 | click or scan EU-EC-10007630767 |  | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 23011 | click or scan EU-EC-10007630619 |  | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23012 | click or scan EU-EC-10007630604 |  | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23013 | click or scan EU-EC-10007630544 |  | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Female | Blood glucose decreased (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23014 | click or scan EU-EC-10007630250 |  | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Female | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23015 | click or scan EU-EC-10007630089 |  | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure congestive (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23016 | click or scan EU-EC-10007629592 |  | 2021-02-16 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23017 | click or scan EU-EC-10007629267 |  | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23018** | click or scan EU-EC-10007629247 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23019** | click or scan EU-EC-10007629221 | | 2021-02-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23020** | click or scan EU-EC-10007628986 | | 2021-02-16 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Cough (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - Life Threatening), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23021** | click or scan EU-EC-10007627253 | | 2021-02-16 | Healthcare Professional | EEA | 65-85 Years | Female | Pyrexia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23022** | click or scan EU-EC-10007627154 | | 2021-02-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (6d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23023** | click or scan EU-EC-10007627122 | | 2021-02-16 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Arthralgia (n/a - Unknown - ), COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Delusion (n/a - Not Recovered/Not Resolved - ), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastric haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23024** | click or scan EU-EC-10007627114 | | 2021-02-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23025** | click or scan EU-EC-10007626621 | | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23026** | click or scan EU-EC-10007626321 | | 2021-02-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23027** | click or scan EU-EC-10007625855 | | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (2d - Recovered/Resolved - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **23028** | click or scan EU-EC-10007625843 | | 2021-02-16 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23029** | click or scan EU-EC-10007625788 | | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Male | Chest discomfort (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vertigo (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **23030** | click or scan EU-EC-10007625650 | | 2021-02-16 | Non Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23031** | click or scan EU-EC-10007625339 | | 2021-02-16 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| **23032** | click or scan EU-EC-10007623255 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23033** | click or scan EU-EC-10007623234 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Headache (1d - Recovered/Resolved - ), Nausea (1d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23034** | click or scan EU-EC-10007622988 | | 2021-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Muscular weakness (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23035** | click or scan EU-EC-10007622617 | | 2021-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Aortic aneurysm (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23036** | click or scan EU-EC-10007622579 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Breath sounds (n/a - Unknown - ), Choking (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Recovered/Resolved - ), Oxygen saturation immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **23037** | click or scan EU-EC-10007622394 | | 2021-02-15 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [1d - n/a - Intramuscular]) |
| **23038** | click or scan EU-EC-10007622335 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23039 | click or scan EU-EC-10007622130 | | 2021-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Ill-defined disorder - Not applicable - [1d - n/a - Intramuscular]) |
| 23040 | click or scan EU-EC-10007622091 | | 2021-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Breath sounds abnormal (n/a - Unknown - Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Somnolence (n/a - Unknown - Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23041 | click or scan EU-EC-10007622087 | | 2021-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23042 | click or scan EU-EC-10007621697 | | 2021-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23043 | click or scan EU-EC-10007621366 | | 2021-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| 23044 | click or scan EU-EC-10007621297 | | 2021-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Heart rate irregular (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23045 | click or scan EU-EC-10007620993 | | 2021-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23046 | click or scan EU-EC-10007620825 | | 2021-02-15 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23047 | click or scan EU-EC-10007620391 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (6d - Fatal - **Results in Death**), Dysstasia (6d - Fatal - **Results in Death**), Fall (6d - Fatal - **Results in Death**), Fibrin D dimer increased (6d - Fatal - **Results in Death**), Liver function test abnormal (6d - Fatal - **Results in Death**), Oxygen saturation decreased (6d - Fatal - **Results in Death**), Troponin increased (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23048 | click or scan EU-EC-10007620259 | | 2021-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23049** | click or scan EU-EC-10007620170 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Lividity (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23050** | click or scan EU-EC-10007620144 | | 2021-02-15 | Healthcare Professional | EEA | Not Specified | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Injection site erythema (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23051** | click or scan EU-EC-10007619797 | | 2021-02-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **23052** | click or scan EU-EC-10007619795 | | 2021-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23053** | click or scan EU-EC-10007619681 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23054** | click or scan EU-EC-10007618663 | | 2021-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23055** | click or scan EU-EC-10007618573 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure acute (5d - Fatal - **Results in Death**), Cardiogenic shock (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23056** | click or scan EU-EC-10007618491 | | 2021-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (4wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23057** | click or scan EU-EC-10007618264 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23058** | click or scan EU-EC-10007618072 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23059** | click or scan EU-EC-10007617973 | | 2021-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23060** | click or scan EU-EC-10007617968 | | 2021-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23061** | click or scan EU-EC-10007617765 | | 2021-02-15 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure abnormal (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23062** | click or scan EU-EC-10007617639 | | 2021-02-15 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23063** | click or scan EU-EC-10007617530 | | 2021-02-15 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23064** | click or scan EU-EC-10007616829 | | 2021-02-15 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia bacterial (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **23065** | click or scan EU-EC-10007612377 | | 2021-02-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **23066** | click or scan EU-EC-10007612344 | | 2021-02-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **23067** | click or scan EU-EC-10007612103 | | 2021-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Balance disorder (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), COVID-19 (2d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Coordination abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23068** | click or scan EU-EC-10007611817 | | 2021-02-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23069** | click or scan EU-EC-10007611508 | | 2021-02-14 | Healthcare Professional | EEA | More than 85 Years | Female | Body temperature increased (1d - Recovered/Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (1d - Recovered/Resolved - ), Myalgia (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23070** | click or scan EU-EC-10007610668 | | 2021-02-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombocytopenia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23071** | click or scan EU-EC-10007610129 | | 2021-02-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **23072** | click or scan EU-EC-10007610105 | | 2021-02-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23073** | click or scan EU-EC-10007608563 | | 2021-02-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23074** | click or scan EU-EC-10007608452 | | 2021-02-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bacterial infection (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fall (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypopnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin exfoliation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **23075** | click or scan EU-EC-10007608442 | | 2021-02-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Dementia (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Pain (n/a - Recovered/Resolved - ), Respiratory tract infection (n/a - Fatal - **Results in Death**), Swelling face (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **23076** | click or scan EU-EC-10007608434 | | 2021-02-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23077** | click or scan EU-EC-10007608186 | | 2021-02-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23078 | click or scan EU-EC-10007608179 |  | 2021-02-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 23079 | click or scan EU-EC-10007608096 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23080 | click or scan EU-EC-10007608035 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 23081 | click or scan EU-EC-10007608030 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Hypertension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23082 | click or scan EU-EC-10007608029 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23083 | click or scan EU-EC-10007608020 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23084 | click or scan EU-EC-10007608011 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23085 | click or scan EU-EC-10007608007 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23086 | click or scan EU-EC-10007607887 |  | 2021-02-13 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Subileus (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23087 | click or scan EU-EC-10007607854 |  | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), FENTANYL [FENTANYL, FENTANYL CITRATE] (S - Pain - Not applicable - [n/a - n/a - Cutaneous]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23088** | click or scan EU-EC-10007607789 | | 2021-02-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23089** | click or scan EU-EC-10007607779 | | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23090** | click or scan EU-EC-10007607762 | | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23091** | click or scan EU-EC-10007607617 | | 2021-02-13 | Healthcare Professional | EEA | 65-85 Years | Male | Acute abdomen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [COLCHICINE] (S - Gouty arthritis - Dose not changed - [n/a - 1 {DF} - Oral]), [DILTIAZEM HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]) |
| **23092** | click or scan EU-EC-10007607610 | | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23093** | click or scan EU-EC-10007607455 | | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23094** | click or scan EU-EC-10007607447 | | 2021-02-13 | Healthcare Professional | EEA | 65-85 Years | Male | Lymphopenia (n/a - Not Recovered/Not Resolved - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23095** | click or scan EU-EC-10007606632 | | 2021-02-13 | Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (11d - Fatal - **Results in Death**), Hyperpyrexia (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23096** | click or scan EU-EC-10007604518 | | 2021-02-12 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| **23097** | click or scan EU-EC-10007604081 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23098** | click or scan EU-EC-10007603914 | | 2021-02-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **23099** | click or scan EU-EC-10007603247 | | 2021-02-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypoxia (n/a - Unknown - Other Medically Important Condition), Lung infiltration (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Respiratory failure (450min - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (1350min - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23100** | click or scan EU-EC-10007603152 | | 2021-02-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23101** | click or scan EU-EC-10007602606 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Not Specified | General physical health deterioration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **23102** | click or scan EU-EC-10007601617 | | 2021-02-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (3d - Fatal - **Results in Death**), Cardiac disorder (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dizziness (2d - Fatal - **Results in Death**), Pain in extremity (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23103** | click or scan EU-EC-10007599728 | | 2021-02-12 | Non Healthcare Professional | EEA | 65-85 Years | Female | Apathy (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Eating disorder (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Fatigue (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Language disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Memory impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23104** | click or scan EU-EC-10007599192 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **23105** | click or scan EU-EC-10007599036 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **23106** | click or scan EU-EC-10007598963 | | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| **23107** | click or scan EU-EC-10007598507 | | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Male | Cough (12d - Fatal - **Results in Death**), Diet refusal (9d - Fatal - **Results in Death**), General physical health deterioration (9d - Fatal - **Results in Death**), Restlessness (12d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23108 | click or scan EU-EC-10007598354 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Asthenia (n/a - Unknown - Other Medically Important Condition), Cardiac death (n/a - Fatal - **Results in Death**), Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23109 | click or scan EU-EC-10007598105 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23110 | click or scan EU-EC-10007598081 | | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular]) |
| 23111 | click or scan EU-EC-10007598076 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Gaze palsy (n/a - Fatal - **Results in Death**), Opisthotonus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23112 | click or scan EU-EC-10007597682 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Death (5d - Fatal - **Results in Death**), General physical health deterioration (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23113 | click or scan EU-EC-10007597273 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23114 | click or scan EU-EC-10007596811 | | 2021-02-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection bacterial (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23115 | click or scan EU-EC-10007596055 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Multi-organ disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23116 | click or scan EU-EC-10007595470 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (5d - Fatal - **Results in Death**), Heart rate increased (5d - Fatal - **Results in Death**), Loss of consciousness (5d - Fatal - **Results in Death**), Oxygen saturation decreased (5d - Fatal - **Results in Death**), Respiratory arrest (5d - Fatal - **Results in Death**), Terminal state (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23117 | click or scan EU-EC-10007594370 | | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23118 | click or scan EU-EC-10007594349 |  | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23119 | click or scan EU-EC-10007594325 |  | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Venous oxygen saturation decreased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23120 | click or scan EU-EC-10007594300 |  | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Drug withdrawn - [n/a - n/a - n/a]) |
| 23121 | click or scan EU-EC-10007594292 |  | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23122 | click or scan EU-EC-10007594275 |  | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23123 | click or scan EU-EC-10007594199 |  | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23124 | click or scan EU-EC-10007594197 |  | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23125 | click or scan EU-EC-10007592490 |  | 2021-02-12 | Healthcare Professional | EEA | 18-64 Years | Not Specified | Asthenia (n/a - Fatal - **Results in Death**), Carotid artery dissection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23126 | click or scan EU-EC-10007589880 |  | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - ), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23127 | click or scan EU-EC-10007589407 |  | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Female | Arrhythmia (n/a - Unknown - **Results in Death**), Cerebrovascular accident (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23128 | click or scan EU-EC-10007589133 |  | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Male | Lung disorder (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23129 | click or scan EU-EC-10007589122 | | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23130 | click or scan EU-EC-10007589120 | | 2021-02-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23131 | click or scan EU-EC-10007588070 | | 2021-02-12 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23132 | click or scan EU-EC-10007590756 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abnormal behaviour (n/a - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Resuscitation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23133 | click or scan EU-EC-10007590678 | | 2021-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23134 | click or scan EU-EC-10007590664 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hip fracture (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23135 | click or scan EU-EC-10007590561 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23136 | click or scan EU-EC-10007590538 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23137 | click or scan EU-EC-10007590534 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23138 | click or scan EU-EC-10007590289 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anal incontinence (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Hypotonia (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23139 | click or scan EU-EC-10007590086 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Intracranial aneurysm (1d - Fatal - **Results in Death**), Pulmonary oedema (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23140 | click or scan EU-EC-10007590071 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23141 | click or scan EU-EC-10007590057 | | 2021-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23142 | click or scan EU-EC-10007589810 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23143 | click or scan EU-EC-10007589809 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23144 | click or scan EU-EC-10007589645 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23145 | click or scan EU-EC-10007589613 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Male | Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (2d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1 {DF} - n/a]) |
| 23146 | click or scan EU-EC-10007589271 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood lactic acid increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart sounds abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23147 | click or scan EU-EC-10007589148 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (19d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23148 | click or scan EU-EC-10007588052 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23149 | click or scan EU-EC-10007588041 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23150 | click or scan EU-EC-10007587973 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Erythema (n/a - Fatal - **Results in Death**), Heart rate increased (3d - Fatal - **Results in Death**), Hyperventilation (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23151 | click or scan EU-EC-10007587932 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23152 | click or scan EU-EC-10007587714 | | 2021-02-11 | Non Healthcare Professional | EEA | More than 85 Years | Female | Drug ineffective (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 23153 | click or scan EU-EC-10007587644 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23154 | click or scan EU-EC-10007587136 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Hypotension (n/a - Fatal - **Results in Death**), Melaena (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23155 | click or scan EU-EC-10007585761 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - n/a]) |
| 23156 | click or scan EU-EC-10007584814 | | 2021-02-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23157 | click or scan EU-EC-10007584512 | | 2021-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cachexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23158 | click or scan EU-EC-10007584469 | | 2021-02-11 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 23159 | click or scan EU-EC-10007584467 | | 2021-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23160 | click or scan EU-EC-10007583472 | | 2021-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 23161 | click or scan EU-EC-10007582961 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (24h - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), General physical condition abnormal (24h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23162 | click or scan EU-EC-10007582929 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23163 | click or scan EU-EC-10007582669 | | 2021-02-11 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23164 | click or scan EU-EC-10007582271 | | 2021-02-11 | Non Healthcare Professional | EEA | Not Specified | Male | Asthenia (6d - Fatal - **Results in Death**), Chills (6d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23165 | click or scan EU-EC-10007581296 | | 2021-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cold sweat (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23166 | click or scan EU-EC-10007580612 | | 2021-02-11 | Healthcare Professional | Non EEA | Not Specified | Male | Cough (n/a - Unknown - Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23167 | click or scan EU-EC-10007580463 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiovascular disorder (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23168 | click or scan EU-EC-10007580407 | | 2021-02-11 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23169 | click or scan EU-EC-10007580314 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Infection (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23170** | click or scan EU-EC-10007579963 | | 2021-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **23171** | click or scan EU-EC-10007579876 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23172** | click or scan EU-EC-10007579874 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23173** | click or scan EU-EC-10007579737 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **23174** | click or scan EU-EC-10007579568 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Confusional state (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Paramnesia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23175** | click or scan EU-EC-10007579510 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **23176** | click or scan EU-EC-10007579349 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23177 | click or scan EU-EC-10007578922 | | 2021-02-11 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), KEPPRA 500 MG FILM-COATED TABLETS [LEVETIRACETAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [FUROSEMIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [OXAZEPAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80-90%] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]), [TIAPRIDE HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 145mg - Oral]), [ZOPICLONE] (S - Product used for unknown indication - Dose not changed - [n/a - 1 {DF} - Oral]) |
| 23178 | click or scan EU-EC-10007578890 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (4h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (4h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (4h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (4h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (4h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23179 | click or scan EU-EC-10007578850 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23180 | click or scan EU-EC-10007578222 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (4d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Decreased appetite (4d - Fatal - **Results in Death**), Grip strength decreased (4d - Fatal - **Results in Death**), Hemiplegia (4d - Fatal - **Results in Death**, Other Medically Important Condition), Hypotonia (4d - Fatal - **Results in Death**), Speech disorder (4d - Fatal - **Results in Death**), Weight decreased (4d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23181 | click or scan EU-EC-10007576024 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23182 | click or scan EU-EC-10007575416 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23183 | click or scan EU-EC-10007575367 | | 2021-02-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23184 | click or scan EU-EC-10007575089 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Female | Abdominal distension (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Anal fistula (n/a - Fatal - **Results in Death**, Life Threatening), General physical health deterioration (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23185 | click or scan EU-EC-10007574895 | | 2021-02-11 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23186 | click or scan EU-EC-10007574015 | | 2021-02-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23187 | click or scan EU-EC-10007573492 | | 2021-02-11 | Non Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary oedema (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23188 | click or scan EU-EC-10007573079 | | 2021-02-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Respiratory depression (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23189 | click or scan EU-EC-10007579444 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23190 | click or scan EU-EC-10007579430 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Posture abnormal (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23191 | click or scan EU-EC-10007579428 | | 2021-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23192 | click or scan EU-EC-10007579213 | | 2021-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23193** | click or scan EU-EC-10007579173 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23194** | click or scan EU-EC-10007578963 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Exposure to SARS-CoV-2 (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23195** | click or scan EU-EC-10007577981 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23196** | click or scan EU-EC-10007577901 | | 2021-02-10 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23197** | click or scan EU-EC-10007577844 | | 2021-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory failure (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23198** | click or scan EU-EC-10007577822 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23199** | click or scan EU-EC-10007577691 | | 2021-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Endotracheal intubation (1d - Fatal - **Results in Death**), Hemiparesis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23200** | click or scan EU-EC-10007577551 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Dyspnoea (4d - Fatal - **Results in Death**, Other Medically Important Condition), Renal failure (4d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23201** | click or scan EU-EC-10007577332 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **23202** | click or scan EU-EC-10007577331 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23203 | click or scan EU-EC-10007577329 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23204 | click or scan EU-EC-10007577327 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23205 | click or scan EU-EC-10007577326 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23206 | click or scan EU-EC-10007577324 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23207 | click or scan EU-EC-10007577313 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23208 | click or scan EU-EC-10007577309 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23209 | click or scan EU-EC-10007577301 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23210 | click or scan EU-EC-10007577300 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23211 | click or scan EU-EC-10007577298 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23212 | click or scan EU-EC-10007577296 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23213 | click or scan EU-EC-10007577294 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23214 | click or scan EU-EC-10007577182 | | 2021-02-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23215 | click or scan EU-EC-10007577139 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23216 | click or scan EU-EC-10007576645 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ), Hypotonia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23217 | click or scan EU-EC-10007576618 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23218 | click or scan EU-EC-10007575826 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23219 | click or scan EU-EC-10007575640 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**), X-ray with contrast (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23220 | click or scan EU-EC-10007575387 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Haematemesis (n/a - Fatal - **Results in Death**), Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23221 | click or scan EU-EC-10007575039 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ileus paralytic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Microcytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23222 | click or scan EU-EC-10007574638 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 23223 | click or scan EU-EC-10007574145 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23224 | click or scan EU-EC-10007573894 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23225 | click or scan EU-EC-10007573862 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23226 | click or scan EU-EC-10007573709 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**), Oral pain (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 23227 | click or scan EU-EC-10007573438 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Arterial occlusive disease (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (8d - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23228 | click or scan EU-EC-10007573236 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Pulse absent (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23229 | click or scan EU-EC-10007573190 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Hypothermia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Unknown]) |
| 23230 | click or scan EU-EC-10007573139 | | 2021-02-10 | Non Healthcare Professional | EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a]) |
| 23231 | click or scan EU-EC-10007573134 | | 2021-02-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Haemorrhagic stroke (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [ACETYLSALICYLIC ACID] (S - n/a - Drug withdrawn - [n/a - n/a - Oral]) |
| 23232 | click or scan EU-EC-10007572882 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulse absent (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23233 | click or scan EU-EC-10007572853 | | 2021-02-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23234 | click or scan EU-EC-10007572756 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | SARS-CoV-2 test positive (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23235 | click or scan EU-EC-10007572729 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (5d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23236 | click or scan EU-EC-10007572288 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Erythema (n/a - Unknown - ), Localised oedema (n/a - Unknown - ), Skin warm (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23237 | click or scan EU-EC-10007571961 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 23238 | click or scan EU-EC-10007571408 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23239 | click or scan EU-EC-10007569602 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Male | Injection site pain (2d - Fatal - **Results in Death**), Myocardial infarction (1d - Fatal - **Results in Death**), Pain (1d - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23240 | click or scan EU-EC-10007568979 | | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23241 | click or scan EU-EC-10007568912 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Fall (16d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23242 | click or scan EU-EC-10007568847 | | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Apnoea (4d - Fatal - **Results in Death**), Cough (4d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23243 | click or scan EU-EC-10007568824 | | 2021-02-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Balance disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23244 | click or scan EU-EC-10007568780 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Superinfection bacterial (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23245 | click or scan EU-EC-10007568772 |  | 2021-02-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (3d - Fatal - **Results in Death**), Left ventricular failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous]) |
| 23246 | click or scan EU-EC-10007568391 |  | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23247 | click or scan EU-EC-10007568359 |  | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 23248 | click or scan EU-EC-10007568351 |  | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23249 | click or scan EU-EC-10007567352 |  | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Male | Thrombotic stroke (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23250 | click or scan EU-EC-10007567271 |  | 2021-02-10 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 23251 | click or scan EU-EC-10007565314 |  | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cholecystitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23252 | click or scan EU-EC-10007565298 |  | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypoperfusion (n/a - Not Recovered/Not Resolved - **Results in Death**), Pain in jaw (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23253 | click or scan EU-EC-10007565255 |  | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Coronavirus infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23254 | click or scan EU-EC-10007565238 |  | 2021-02-10 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Lip oedema (n/a - Recovering/Resolving - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23255 | click or scan EU-EC-10007565174 | | 2021-02-10 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23256 | click or scan EU-EC-10007564755 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23257 | click or scan EU-EC-10007564737 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (15min - Unknown - ), Pallor (15min - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23258 | click or scan EU-EC-10007564118 | | 2021-02-09 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | ADALIMUMAB [ADALIMUMAB] (S - Crohn's disease - Drug withdrawn - [325d - 40mg - Subcutaneous]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 23259 | click or scan EU-EC-10007563659 | | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23260 | click or scan EU-EC-10007562787 | | 2021-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23261 | click or scan EU-EC-10007562698 | | 2021-02-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23262 | click or scan EU-EC-10007562600 | | 2021-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23263 | click or scan EU-EC-10007562136 | | 2021-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23264 | click or scan EU-EC-10007561989 | | 2021-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23265 | click or scan EU-EC-10007561974 | | 2021-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23266** | click or scan EU-EC-10007561548 | | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23267** | click or scan EU-EC-10007560832 | | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Sepsis (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23268** | click or scan EU-EC-10007560641 | | 2021-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **23269** | click or scan EU-EC-10007560610 | | 2021-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23270** | click or scan EU-EC-10007560443 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **23271** | click or scan EU-EC-10007560292 | | 2021-02-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23272** | click or scan EU-EC-10007560068 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **23273** | click or scan EU-EC-10007560067 | | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23274** | click or scan EU-EC-10007559705 | | 2021-02-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23275** | click or scan EU-EC-10007559219 | | 2021-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23276 | click or scan EU-EC-10007559218 |  | 2021-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23277 | click or scan EU-EC-10007559165 |  | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| 23278 | click or scan EU-EC-10007559149 |  | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23279 | click or scan EU-EC-10007558916 |  | 2021-02-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23280 | click or scan EU-EC-10007558909 |  | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23281 | click or scan EU-EC-10007558883 |  | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23282 | click or scan EU-EC-10007558807 |  | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Dehydration (1d - Fatal - **Results in Death**), Depressed level of consciousness (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Erythema (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23283 | click or scan EU-EC-10007558643 |  | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23284 | click or scan EU-EC-10007558601 |  | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23285 | click or scan EU-EC-10007558544 |  | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23286** | click or scan EU-EC-10007558440 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| **23287** | click or scan EU-EC-10007558334 | | 2021-02-09 | Healthcare Professional | EEA | Not Specified | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **23288** | click or scan EU-EC-10007558333 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **23289** | click or scan EU-EC-10007558332 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Bronchopneumopathy (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **23290** | click or scan EU-EC-10007558108 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23291** | click or scan EU-EC-10007558047 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23292** | click or scan EU-EC-10007557616 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23293** | click or scan EU-EC-10007557613 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rales (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23294** | click or scan EU-EC-10007557115 | | 2021-02-09 | Healthcare Professional | EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23295** | click or scan EU-EC-10007557069 | | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**), Cardiovascular disorder (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23296** | click or scan EU-EC-10007557025 | | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Myocardial infarction (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23297** | click or scan EU-EC-10007556452 | | 2021-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Off label use (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Virologic failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23298** | click or scan EU-EC-10007556440 | | 2021-02-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23299** | click or scan EU-EC-10007555566 | | 2021-02-09 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a]) |
| **23300** | click or scan EU-EC-10007551665 | | 2021-02-08 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23301** | click or scan EU-EC-10007551029 | | 2021-02-08 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23302** | click or scan EU-EC-10007550042 | | 2021-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23303** | click or scan EU-EC-10007549625 | | 2021-02-08 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a]) |
| **23304** | click or scan EU-EC-10007549203 | | 2021-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **23305** | click or scan EU-EC-10007548767 | | 2021-02-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]), XARELTO [RIVAROXABAN] (S - n/a - n/a - [n/a - 10mg - n/a]) |
| **23306** | click or scan EU-EC-10007548481 | | 2021-02-08 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Unknown - ), Cerebral haemorrhage (0d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23307 | click or scan EU-EC-10007547940 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Bronchitis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23308 | click or scan EU-EC-10007547320 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cyanosis (n/a - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 23309 | click or scan EU-EC-10007546642 | | 2021-02-08 | Healthcare Professional | EEA | 18-64 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23310 | click or scan EU-EC-10007546548 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (7d - Fatal - **Results in Death**), Diet refusal (7d - Fatal - **Results in Death**), Disturbance in attention (7d - Fatal - **Results in Death**), Hyporesponsive to stimuli (7d - Fatal - **Results in Death**), Hypotension (7d - Fatal - **Results in Death**), Stupor (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23311 | click or scan EU-EC-10007546319 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23312 | click or scan EU-EC-10007545629 | | 2021-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Arteriosclerosis (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Atrophy (n/a - Fatal - **Results in Death**), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Embolism (n/a - Fatal - **Results in Death**), Gastric disorder (n/a - Fatal - **Results in Death**), Hepatic cirrhosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23313 | click or scan EU-EC-10007544752 | | 2021-02-08 | Non Healthcare Professional | EEA | 65-85 Years | Female | Malaise (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23314 | click or scan EU-EC-10007543904 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Male | Agitation (0d - Fatal - **Results in Death**), Cardiovascular disorder (0d - Fatal - **Results in Death**), Confusional state (0d - Fatal - **Results in Death**), Dyspnoea (0d - Fatal - **Results in Death**), Hypotension (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Neutropenia (0d - Fatal - **Results in Death**), Oxygen saturation decreased (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**), Respiratory disorder (0d - Fatal - **Results in Death**), Tachycardia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23315 | click or scan EU-EC-10007543875 | | 2021-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Asthma (n/a - Fatal - **Results in Death**), Cardiac asthma (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23316 | click or scan EU-EC-10007543864 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23317 | click or scan EU-EC-10007543856 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Ileus - Dose not changed - [n/a - 1000mg - n/a]), [NOT AVAILABLE] (S - Ileus, Pneumonia - Dose increased - [n/a - 1 {DF} - n/a]), [NOT AVAILABLE] (S - Palliative care - Dose not changed - [n/a - 10mg - n/a]) |
| 23318 | click or scan EU-EC-10007543767 | | 2021-02-08 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal dilatation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23319 | click or scan EU-EC-10007543763 | | 2021-02-08 | Healthcare Professional | EEA | 18-64 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| 23320 | click or scan EU-EC-10007543726 | | 2021-02-08 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23321 | click or scan EU-EC-10007543660 | | 2021-02-08 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23322 | click or scan EU-EC-10007543641 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Apathy (4d - Fatal - **Results in Death**, Life Threatening), Bradycardia (4d - Fatal - **Results in Death**, Life Threatening), Bronchitis (4d - Fatal - **Results in Death**, Life Threatening), Death (4d - Fatal - **Results in Death**, Life Threatening), Febrile infection (4d - Fatal - **Results in Death**, Life Threatening), Rhonchi (4d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23323 | click or scan EU-EC-10007542952 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Male | Heart rate decreased (3d - Fatal - **Results in Death**), Oxygen saturation decreased (3d - Fatal - **Results in Death**), Productive cough (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23324 | click or scan EU-EC-10007542928 | | 2021-02-08 | Healthcare Professional | EEA | More than 85 Years | Female | Apnoea (6d - Fatal - **Results in Death**), Bedridden (6d - Fatal - **Results in Death**), Dizziness (1d - Fatal - **Results in Death**), Dyspnoea (11d - Fatal - **Results in Death**), General physical health deterioration (14d - Fatal - **Results in Death**), Muscular weakness (11d - Fatal - **Results in Death**), Syncope (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23325 | click or scan EU-EC-10007542918 | | 2021-02-08 | Healthcare Professional | EEA | 65-85 Years | Female | Decreased appetite (5d - Fatal - **Results in Death**), Depressed level of consciousness (5d - Fatal - **Results in Death**), General physical health deterioration (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23326 | click or scan EU-EC-10007541938 | | 2021-02-08 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Hypertension (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23327 | click or scan EU-EC-10007541791 | | 2021-02-08 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23328 | click or scan EU-EC-10007540868 | | 2021-02-07 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23329 | click or scan EU-EC-10007540748 | | 2021-02-07 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Paralysis (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23330 | click or scan EU-EC-10007538569 | | 2021-02-06 | Healthcare Professional | EEA | More than 85 Years | Female | Body temperature increased (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23331 | click or scan EU-EC-10007537763 | | 2021-02-06 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23332 | click or scan EU-EC-10007536258 | | 2021-02-06 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Recovered/Resolved - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23333 | click or scan EU-EC-10007535469 | | 2021-02-06 | Healthcare Professional | EEA | 65-85 Years | Female | Laryngeal dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23334 | click or scan EU-EC-10007535306 | | 2021-02-06 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Haematemesis (1d - Fatal - **Results in Death**), Pneumonia aspiration (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23335 | click or scan EU-EC-10007535205 | | 2021-02-06 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23336 | click or scan EU-EC-10007535957 | | 2021-02-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Vomiting (11d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23337 | click or scan EU-EC-10007535504 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23338 | click or scan EU-EC-10007534973 | | 2021-02-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Bedridden (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23339 | click or scan EU-EC-10007534567 | | 2021-02-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Body temperature increased (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Nausea (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23340 | click or scan EU-EC-10007534293 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23341 | click or scan EU-EC-10007534113 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| 23342 | click or scan EU-EC-10007532699 | | 2021-02-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23343 | click or scan EU-EC-10007532191 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 23344 | click or scan EU-EC-10007531483 | | 2021-02-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23345 | click or scan EU-EC-10007531445 | | 2021-02-05 | Non Healthcare Professional | Non EEA | Not Specified | Female | Anxiety (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23346 | click or scan EU-EC-10007531410 | | 2021-02-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23347 | click or scan EU-EC-10007531045 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Anaphylactic reaction (2d - Fatal - **Results in Death**), Cardio-respiratory arrest (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Hypotension (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23348 | click or scan EU-EC-10007530369 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), SARS-CoV-2 sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23349 | click or scan EU-EC-10007530163 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23350 | click or scan EU-EC-10007528827 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Male | General physical condition abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23351 | click or scan EU-EC-10007528631 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Upper respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23352 | click or scan EU-EC-10007528461 | | 2021-02-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23353 | click or scan EU-EC-10007528378 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Interleukin level increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| 23354 | click or scan EU-EC-10007528194 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23355 | click or scan EU-EC-10007528105 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiogenic shock (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23356 | click or scan EU-EC-10007527990 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (5d - Fatal - **Results in Death**), Loss of consciousness (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23357 | click or scan EU-EC-10007527560 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23358 | click or scan EU-EC-10007527303 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23359 | click or scan EU-EC-10007526844 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (1d - Unknown - ), Cold sweat (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23360 | click or scan EU-EC-10007526767 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Oxygen saturation decreased (1d - Fatal - **Results in Death**), Urinary tract infection (1d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23361 | click or scan EU-EC-10007526750 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), General physical health deterioration (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23362 | click or scan EU-EC-10007526731 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Male | Decreased appetite (5d - Fatal - **Results in Death**), Dysphagia (5d - Fatal - **Results in Death**), Fatigue (5d - Fatal - **Results in Death**), General physical health deterioration (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23363 | click or scan EU-EC-10007526658 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23364 | click or scan EU-EC-10007524533 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23365 | click or scan EU-EC-10007524506 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23366 | click or scan EU-EC-10007524469 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23367 | click or scan EU-EC-10007524454 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23368** | click or scan EU-EC-10007524390 | | 2021-02-05 | Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (6d - Fatal - **Results in Death**), Generalised oedema (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), GALVUS 50 MG TABLETS [VILDAGLIPTIN] (S - Type 2 diabetes mellitus - n/a - [n/a - 50mg - Oral]) |
| **23369** | click or scan EU-EC-10007523214 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **23370** | click or scan EU-EC-10007522843 | | 2021-02-05 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23371** | click or scan EU-EC-10007523917 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Male | Anuria (n/a - Fatal - **Results in Death**), Asthenia (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Respiratory tract infection (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23372** | click or scan EU-EC-10007520916 | | 2021-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Hypernatraemia (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), NOVORAPID [INSULIN ASPART] (S - n/a - n/a - [n/a - n/a - n/a]), [CEFTRIAXONE] (S - Lung disorder - Dose not changed - [n/a - 2g - Intravenous (not otherwise specified)]) |
| **23373** | click or scan EU-EC-10007519764 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23374** | click or scan EU-EC-10007518556 | | 2021-02-04 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **23375** | click or scan EU-EC-10007518409 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Chronic kidney disease (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Urticaria (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23376** | click or scan EU-EC-10007518287 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Psoriasis (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23377** | click or scan EU-EC-10007518276 | | 2021-02-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradycardia (n/a - Unknown - Other Medically Important Condition), Bundle branch block right (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Hypothermia (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - ), Pulseless electrical activity (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23378 | click or scan EU-EC-10007516473 | | 2021-02-04 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23379 | click or scan EU-EC-10007516465 | | 2021-02-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23380 | click or scan EU-EC-10007516399 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23381 | click or scan EU-EC-10007516334 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23382 | click or scan EU-EC-10007516151 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23383 | click or scan EU-EC-10007516122 | | 2021-02-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23384 | click or scan EU-EC-10007516030 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23385 | click or scan EU-EC-10007515962 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (45min - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| 23386 | click or scan EU-EC-10007515914 | | 2021-02-04 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23387 | click or scan EU-EC-10007515888 | | 2021-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | Adult failure to thrive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23388 | click or scan EU-EC-10007515751 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23389** | click or scan EU-EC-10007515744 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **23390** | click or scan EU-EC-10007515738 | | 2021-02-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23391** | click or scan EU-EC-10007512509 | | 2021-02-04 | Healthcare Professional | EEA | More than 85 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23392** | click or scan EU-EC-10007511116 | | 2021-02-03 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **23393** | click or scan EU-EC-10007508427 | | 2021-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23394** | click or scan EU-EC-10007508333 | | 2021-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23395** | click or scan EU-EC-10007508322 | | 2021-02-03 | Non Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **23396** | click or scan EU-EC-10007508102 | | 2021-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Increased upper airway secretion (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **23397** | click or scan EU-EC-10007507436 | | 2021-02-03 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), OLANZAPINE 10 MG [OLANZAPINE] (S - n/a - Unknown - [n/a - n/a - n/a]), [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23398 | click or scan EU-EC-10007507351 | | 2021-02-03 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (3d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Hyperpyrexia (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23399 | click or scan EU-EC-10007506691 | | 2021-02-03 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23400 | click or scan EU-EC-10007506524 | | 2021-02-03 | Healthcare Professional | EEA | 65-85 Years | Female | SARS-CoV-2 test positive (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23401 | click or scan EU-EC-10007506497 | | 2021-02-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (1d - Fatal - **Results in Death**), Resuscitation (1d - Fatal - **Results in Death**), Toxicity to various agents (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23402 | click or scan EU-EC-10007506077 | | 2021-02-03 | Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Poor quality sleep (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23403 | click or scan EU-EC-10007505560 | | 2021-02-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anxiety (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23404 | click or scan EU-EC-10007504344 | | 2021-02-03 | Healthcare Professional | EEA | 65-85 Years | Male | Incorrect route of product administration (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous]) |
| 23405 | click or scan EU-EC-10007504129 | | 2021-02-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Lymph node pain (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 23406 | click or scan EU-EC-10007503900 | | 2021-02-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal tenderness (n/a - Unknown - Other Medically Important Condition), Blood creatinine increased (n/a - Unknown - Other Medically Important Condition), Blood urea increased (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Hyponatraemia (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Intestinal perforation (n/a - Fatal - **Results in Death**), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - Other Medically Important Condition), Movement disorder (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23407 | click or scan EU-EC-10007503324 | | 2021-02-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23408 | click or scan EU-EC-10007502929 |  | 2021-02-03 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23409 | click or scan EU-EC-10007502908 |  | 2021-02-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23410 | click or scan EU-EC-10007502904 |  | 2021-02-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23411 | click or scan EU-EC-10007502281 |  | 2021-02-03 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (0d - Fatal - **Results in Death**), Renal failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23412 | click or scan EU-EC-10007500307 |  | 2021-02-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Foaming at mouth (1d - Fatal - **Results in Death**), Pain in extremity (1d - Fatal - **Results in Death**), Pallor (1d - Fatal - **Results in Death**), Pulse absent (1d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**), Somnolence (1d - Fatal - **Results in Death**), Unresponsive to stimuli (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23413 | click or scan EU-EC-10007499182 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23414 | click or scan EU-EC-10007499124 |  | 2021-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23415 | click or scan EU-EC-10007498569 |  | 2021-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23416 | click or scan EU-EC-10007494983 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23417 | click or scan EU-EC-10007494527 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23418 | click or scan EU-EC-10007494357 |  | 2021-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23419** | click or scan EU-EC-10007494159 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23420** | click or scan EU-EC-10007494036 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23421** | click or scan EU-EC-10007493759 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23422** | click or scan EU-EC-10007493213 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **23423** | click or scan EU-EC-10007492097 |  | 2021-02-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23424** | click or scan EU-EC-10007490796 |  | 2021-02-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **23425** | click or scan EU-EC-10007490642 |  | 2021-02-02 | Healthcare Professional | EEA | 65-85 Years | Female | Hypersensitivity (4d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23426** | click or scan EU-EC-10007490333 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| **23427** | click or scan EU-EC-10007490332 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| **23428** | click or scan EU-EC-10007490160 |  | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23429 | click or scan EU-EC-10007490106 | | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23430 | click or scan EU-EC-10007489318 | | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Acute pulmonary oedema (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23431 | click or scan EU-EC-10007489257 | | 2021-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23432 | click or scan EU-EC-10007489164 | | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23433 | click or scan EU-EC-10007489118 | | 2021-02-02 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23434 | click or scan EU-EC-10007489104 | | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular]) |
| 23435 | click or scan EU-EC-10007489053 | | 2021-02-02 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23436 | click or scan EU-EC-10007488886 | | 2021-02-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain lower (1d - Unknown - Other Medically Important Condition), Axillary pain (1d - Unknown - Other Medically Important Condition), Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (1d - Unknown - Other Medically Important Condition), Myalgia (1d - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23437 | click or scan EU-EC-10007488513 | | 2021-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Recovered/Resolved - ), Pain (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23438 | click or scan EU-EC-10007487604 | | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Diarrhoea (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 23439 | click or scan EU-EC-10007487241 | | 2021-02-01 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23440 | click or scan EU-EC-10007487097 |  | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | Upper gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a]) |
| 23441 | click or scan EU-EC-10007487006 |  | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23442 | click or scan EU-EC-10007486558 |  | 2021-02-01 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypertensive emergency (n/a - Recovered/Resolved - Other Medically Important Condition), Pain (1d - Unknown - Other Medically Important Condition), Rales (1d - Unknown - ), Somnolence (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23443 | click or scan EU-EC-10007486506 |  | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23444 | click or scan EU-EC-10007485871 |  | 2021-02-01 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic infarction (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23445 | click or scan EU-EC-10007485695 |  | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (3d - Recovering/Resolving - ), Rash (3d - Recovering/Resolving - ), Respiratory failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23446 | click or scan EU-EC-10007485543 |  | 2021-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiopulmonary failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23447 | click or scan EU-EC-10007485090 |  | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Male | Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23448 | click or scan EU-EC-10007484526 |  | 2021-02-01 | Healthcare Professional | EEA | 65-85 Years | Male | Dementia (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramedullar (bone marrow)]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23449 | click or scan EU-EC-10007484361 | | 2021-02-01 | Healthcare Professional | EEA | Not Specified | Not Specified | Nausea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23450 | click or scan EU-EC-10007483682 | | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23451 | click or scan EU-EC-10007482017 | | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23452 | click or scan EU-EC-10007481943 | | 2021-02-01 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23453 | click or scan EU-EC-10007481923 | | 2021-02-01 | Healthcare Professional | EEA | 18-64 Years | Male | Foaming at mouth (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Rash erythematous (n/a - Fatal - **Results in Death**), Respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23454 | click or scan EU-EC-10007481912 | | 2021-02-01 | Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Pyelonephritis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**), Vaccination site erythema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23455 | click or scan EU-EC-10007481907 | | 2021-02-01 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23456 | click or scan EU-EC-10007481782 | | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| 23457 | click or scan EU-EC-10007481754 | | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | Increased upper airway secretion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23458 | click or scan EU-EC-10007481458 | | 2021-02-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23459 | click or scan EU-EC-10007480253 | | 2021-02-01 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23460 | click or scan EU-EC-10007480165 | | 2021-02-01 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical condition abnormal (22d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23461 | click or scan EU-EC-10007480110 | | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23462 | click or scan EU-EC-10007480038 | | 2021-02-01 | Healthcare Professional | EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Respiratory tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23463 | click or scan EU-EC-10007479649 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain (n/a - Unknown - ), Anal haemorrhage (n/a - Unknown - ), Back pain (n/a - Recovered/Resolved - ), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23464 | click or scan EU-EC-10007479399 | | 2021-02-01 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| 23465 | click or scan EU-EC-10007478748 | | 2021-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypersensitivity pneumonitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23466 | click or scan EU-EC-10007478598 | | 2021-02-01 | Non Healthcare Professional | Non EEA | Not Specified | Male | Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23467 | click or scan EU-EC-10007478505 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23468 | click or scan EU-EC-10007478392 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23469** | click or scan EU-EC-10007478389 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23470** | click or scan EU-EC-10007478383 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal adhesions (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Postoperative ileus (n/a - Unknown - Caused/Prolonged Hospitalisation), Small intestinal obstruction (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **23471** | click or scan EU-EC-10007478376 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23472** | click or scan EU-EC-10007478370 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23473** | click or scan EU-EC-10007478364 | | 2021-02-01 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23474** | click or scan EU-EC-10007478358 | | 2021-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Female | Facial paralysis (n/a - Unknown - Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23475** | click or scan EU-EC-10007478004 | | 2021-02-01 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiovascular disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **23476** | click or scan EU-EC-10007477988 | | 2021-02-01 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23477** | click or scan EU-EC-10007477956 | | 2021-02-01 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23478** | click or scan EU-EC-10007477398 | | 2021-01-31 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23479 | click or scan EU-EC-10007477354 |  | 2021-01-31 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| 23480 | click or scan EU-EC-10007474085 |  | 2021-01-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (5d - Fatal - **Results in Death**), General physical health deterioration (5d - Fatal - **Results in Death**), Influenza like illness (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23481 | click or scan EU-EC-10007474006 |  | 2021-01-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (23d - Fatal - **Results in Death**), Pyrexia (23d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - n/a - Intramuscular]) |
| 23482 | click or scan EU-EC-10007473506 |  | 2021-01-30 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (1d - Fatal - **Results in Death**, Life Threatening), Vomiting (1d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23483 | click or scan EU-EC-10007473481 |  | 2021-01-30 | Healthcare Professional | EEA | 65-85 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Myocardial ischaemia - Drug withdrawn - [n/a - 75mg - Oral]) |
| 23484 | click or scan EU-EC-10007473418 |  | 2021-01-30 | Healthcare Professional | EEA | 18-64 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23485 | click or scan EU-EC-10007473417 |  | 2021-01-30 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (1d - Not Recovered/Not Resolved - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23486 | click or scan EU-EC-10007473313 |  | 2021-01-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23487 | click or scan EU-EC-10007473305 |  | 2021-01-30 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23488 | click or scan EU-EC-10007471240 |  | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23489** | click or scan EU-EC-10007471030 | | 2021-01-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood creatinine increased (n/a - Unknown - Other Medically Important Condition), Blood urea increased (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Erythema (n/a - Unknown - ), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Leukocytosis (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23490** | click or scan EU-EC-10007471013 | | 2021-01-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | [NOT AVAILABLE] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **23491** | click or scan EU-EC-10007470767 | | 2021-01-29 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **23492** | click or scan EU-EC-10007470732 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (2h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - 1 {DF} - Intramuscular]) |
| **23493** | click or scan EU-EC-10007468930 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23494** | click or scan EU-EC-10007468439 | | 2021-01-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Nasopharyngitis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23495** | click or scan EU-EC-10007467705 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia aspiration (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23496** | click or scan EU-EC-10007467690 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | Arrhythmia (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **23497** | click or scan EU-EC-10007467491 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23498** | click or scan EU-EC-10007467421 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23499** | click or scan EU-EC-10007467145 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23500** | click or scan EU-EC-10007467137 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23501** | click or scan EU-EC-10007467009 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Altered state of consciousness (6d - Fatal - **Results in Death**), Decreased appetite (6d - Fatal - **Results in Death**), Nausea (2d - Recovered/Resolved - ), Pain (2d - Recovered/Resolved - ), Pain (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23502** | click or scan EU-EC-10007466653 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **23503** | click or scan EU-EC-10007466534 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Infection (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **23504** | click or scan EU-EC-10007465789 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **23505** | click or scan EU-EC-10007465770 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23506** | click or scan EU-EC-10007465596 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23507** | click or scan EU-EC-10007465196 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23508** | click or scan EU-EC-10007465137 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23509 | click or scan EU-EC-10007464822 | | 2021-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23510 | click or scan EU-EC-10007464769 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23511 | click or scan EU-EC-10007464544 | | 2021-01-29 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cyanosis (n/a - Unknown - **Results in Death**), General physical health deterioration (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Unknown - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23512 | click or scan EU-EC-10007464525 | | 2021-01-29 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| 23513 | click or scan EU-EC-10007463995 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Body temperature increased (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23514 | click or scan EU-EC-10007463086 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23515 | click or scan EU-EC-10007463020 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Circulatory collapse (4h - Fatal - **Results in Death**, Life Threatening), Peripheral vascular disorder (4h - Fatal - **Results in Death**, Life Threatening), Vomiting (4h - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23516 | click or scan EU-EC-10007462774 | | 2021-01-29 | Healthcare Professional | EEA | Not Specified | Male | Dyspnoea (0d - Fatal - **Results in Death**), General physical health deterioration (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 23517 | click or scan EU-EC-10007462635 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23518 | click or scan EU-EC-10007462633 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23519 | click or scan EU-EC-10007462621 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Male | C-reactive protein increased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| 23520 | click or scan EU-EC-10007461994 | | 2021-01-29 | Healthcare Professional | EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23521 | click or scan EU-EC-10007461911 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23522 | click or scan EU-EC-10007461907 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23523 | click or scan EU-EC-10007461779 | | 2021-01-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23524 | click or scan EU-EC-10007461769 | | 2021-01-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23525 | click or scan EU-EC-10007460233 | | 2021-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23526 | click or scan EU-EC-10007459364 | | 2021-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Diabetic ketoacidosis (n/a - Fatal - **Results in Death**) | [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23527 | click or scan EU-EC-10007459357 | | 2021-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Infection (n/a - Fatal - **Results in Death**) | [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23528 | click or scan EU-EC-10007459216 | | 2021-01-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | [NOT AVAILABLE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23529 | click or scan EU-EC-10007458683 | | 2021-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23530 | click or scan EU-EC-10007458677 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23531 | click or scan EU-EC-10007458215 | | 2021-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Disabling) | [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23532 | click or scan EU-EC-10007457256 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [DOMPERIDONE] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| 23533 | click or scan EU-EC-10007457033 | | 2021-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | Atrioventricular block complete (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23534 | click or scan EU-EC-10007456951 | | 2021-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (7d - Fatal - **Results in Death**, Other Medically Important Condition), Influenza like illness (7d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Unknown]) |
| 23535 | click or scan EU-EC-10007456370 | | 2021-01-28 | Healthcare Professional | EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23536 | click or scan EU-EC-10007456258 | | 2021-01-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rales (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23537 | click or scan EU-EC-10007455924 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23538 | click or scan EU-EC-10007455828 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Circulatory collapse (4h - Fatal - **Results in Death**), Peripheral vascular disorder (4h - Fatal - **Results in Death**), Vomiting (4h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23539 | click or scan EU-EC-10007455769 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (2d - Fatal - **Results in Death**), Acute respiratory failure (2d - Fatal - **Results in Death**), General physical health deterioration (2d - Fatal - **Results in Death**), Hypoxia (0d - Fatal - **Results in Death**), Oxygen saturation decreased (2d - Fatal - **Results in Death**), Pneumonia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23540 | click or scan EU-EC-10007453875 | | 2021-01-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Malaise (2d - Fatal - **Results in Death**), Oxygen saturation decreased (2d - Fatal - **Results in Death**), Pneumonia (2d - Fatal - **Results in Death**), Respiratory disorder (2d - Fatal - **Results in Death**), Sedation (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23541 | click or scan EU-EC-10007453289 | | 2021-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | General physical condition abnormal (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [14d - n/a - Subcutaneous]) |
| 23542 | click or scan EU-EC-10007452967 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Male | Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 23543 | click or scan EU-EC-10007452952 | | 2021-01-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23544 | click or scan EU-EC-10007452681 | | 2021-01-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Respiratory distress (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 23545 | click or scan EU-EC-10007451827 | | 2021-01-28 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cholecystitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23546 | click or scan EU-EC-10007451705 | | 2021-01-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23547 | click or scan EU-EC-10007451467 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23548 | click or scan EU-EC-10007451396 | | 2021-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23549 | click or scan EU-EC-10007451324 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23550 | click or scan EU-EC-10007451287 | | 2021-01-28 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]), NEOFORDEX [DEXAMETHASONE] (S - Monoclonal gammopathy - Not applicable - [n/a - n/a - Oral]), REVLIMID 5 MG HARD CAPSULES [LENALIDOMIDE] (S - Monoclonal gammopathy - Not applicable - [n/a - 5g - Oral]) |
| 23551 | click or scan EU-EC-10007451273 | | 2021-01-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute respiratory failure (2d - Fatal - **Results in Death**), Arrhythmia (2d - Fatal - **Results in Death**), Atrial fibrillation (1d - Recovered/Resolved - **Results in Death**), Metabolic acidosis (2d - Fatal - **Results in Death**), Pneumonia aspiration (2d - Fatal - **Results in Death**), Ventricular fibrillation (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23552 | click or scan EU-EC-10007451255 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (1d - Fatal - **Results in Death**), Malaise (1d - Not Recovered/Not Resolved - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23553 | click or scan EU-EC-10007450992 | | 2021-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23554 | click or scan EU-EC-10007450888 | | 2021-01-28 | Healthcare Professional | EEA | More than 85 Years | Male | Blood pressure inadequately controlled (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - ) | AFLIBERCEPT [AFLIBERCEPT] (S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [CALCIUM FOLINATE, CALCIUM FOLINATE PENTAHYDRATE, FOLINIC ACID] (S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)]), [FLUOROURACIL] (S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)]), [IRINOTECAN, IRINOTECAN HYDROCHLORIDE, IRINOTECAN HYDROCHLORIDE TRIHYDRATE] (S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)]) |
| 23555 | click or scan EU-EC-10007450884 | | 2021-01-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23556 | click or scan EU-EC-10007450134 | | 2021-01-27 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23557 | click or scan EU-EC-10007448078 |  | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23558 | click or scan EU-EC-10007448076 |  | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Acute left ventricular failure (n/a - Fatal - **Results in Death**), Presyncope (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23559 | click or scan EU-EC-10007447492 |  | 2021-01-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 23560 | click or scan EU-EC-10007446887 |  | 2021-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Productive cough (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23561 | click or scan EU-EC-10007446873 |  | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 23562 | click or scan EU-EC-10007446863 |  | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23563 | click or scan EU-EC-10007446819 |  | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23564 | click or scan EU-EC-10007445740 |  | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23565 | click or scan EU-EC-10007445686 |  | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23566 | click or scan EU-EC-10007445410 |  | 2021-01-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (5d - Fatal - **Results in Death**), General physical condition abnormal (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23567 | click or scan EU-EC-10007445290 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | No reaction on previous exposure to drug (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23568 | click or scan EU-EC-10007445236 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| 23569 | click or scan EU-EC-10007445203 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 23570 | click or scan EU-EC-10007445192 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23571 | click or scan EU-EC-10007445158 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23572 | click or scan EU-EC-10007444997 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Personality change (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23573 | click or scan EU-EC-10007444862 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23574 | click or scan EU-EC-10007444664 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23575 | click or scan EU-EC-10007444663 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23576 | click or scan EU-EC-10007442718 | | 2021-01-27 | Healthcare Professional | EEA | 18-64 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23577** | click or scan EU-EC-10007442493 | | 2021-01-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23578** | click or scan EU-EC-10007442460 | | 2021-01-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23579** | click or scan EU-EC-10007442305 | | 2021-01-27 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23580** | click or scan EU-EC-10007441870 | | 2021-01-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **23581** | click or scan EU-EC-10007441212 | | 2021-01-27 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Increased bronchial secretion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [FENTANYL] (S - Pain - Dose not changed - [n/a - .012mg - Transdermal]) |
| **23582** | click or scan EU-EC-10007441175 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **23583** | click or scan EU-EC-10007441084 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23584** | click or scan EU-EC-10007440868 | | 2021-01-27 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23585** | click or scan EU-EC-10007440863 | | 2021-01-27 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **23586** | click or scan EU-EC-10007440246 | | 2021-01-26 | Healthcare Professional | EEA | 18-64 Years | Female | Aortic dissection (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23587** | click or scan EU-EC-10007437980 | | 2021-01-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23588 | click or scan EU-EC-10007437846 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (0d - Fatal - **Results in Death**), Cardiovascular disorder (0d - Fatal - **Results in Death**), General physical health deterioration (0d - Fatal - **Results in Death**), Pulmonary oedema (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23589 | click or scan EU-EC-10007437454 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Respiratory depression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23590 | click or scan EU-EC-10007437448 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23591 | click or scan EU-EC-10007437189 | | 2021-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23592 | click or scan EU-EC-10007436592 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Pancreatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23593 | click or scan EU-EC-10007436350 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 23594 | click or scan EU-EC-10007436275 | | 2021-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23595 | click or scan EU-EC-10007436240 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Haemorrhage intracranial (0d - Fatal - **Results in Death**), Nervous system disorder (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), XARELTO 15 MG [RIVAROXABAN] (S - n/a - Unknown - [n/a - 1 {DF} - n/a]) |
| 23596 | click or scan EU-EC-10007434914 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Dyspnoea (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23597 | click or scan EU-EC-10007433980 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23598 | click or scan EU-EC-10007433690 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23599 | click or scan EU-EC-10007433053 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure immeasurable (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Personality change (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23600 | click or scan EU-EC-10007432561 | | 2021-01-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23601 | click or scan EU-EC-10007432502 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23602 | click or scan EU-EC-10007432271 | | 2021-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| 23603 | click or scan EU-EC-10007431602 | | 2021-01-26 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23604 | click or scan EU-EC-10007431311 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| 23605 | click or scan EU-EC-10007431298 | | 2021-01-26 | Healthcare Professional | EEA | 65-85 Years | Male | Agitation (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), [AMOXICILLIN SODIUM, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM CLAVULANATE] (S - Bronchitis - n/a - [n/a - 1 g - Oral]), [PREDNISOLONE, PREDNISOLONE METASULFOBENZOATE SODIUM] (S - Bronchitis - n/a - [n/a - 40mg - Oral]) |
| 23606 | click or scan EU-EC-10007431178 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23607 | click or scan EU-EC-10007431177 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23608 | click or scan EU-EC-10007431170 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Gastric volvulus (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23609 | click or scan EU-EC-10007431167 | | 2021-01-26 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23610 | click or scan EU-EC-10007431098 | | 2021-01-26 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23611 | click or scan EU-EC-10007431082 | | 2021-01-26 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intravenous (not otherwise specified)]) |
| 23612 | click or scan EU-EC-10007430329 | | 2021-01-25 | Healthcare Professional | EEA | 65-85 Years | Male | Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 23613 | click or scan EU-EC-10007429960 | | 2021-01-25 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| 23614 | click or scan EU-EC-10007427048 | | 2021-01-25 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23615 | click or scan EU-EC-10007423826 | | 2021-01-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (16d - Fatal - **Results in Death**), Death (16d - Fatal - **Results in Death**), General physical condition abnormal (16d - Fatal - **Results in Death**), Pain (16d - Fatal - **Results in Death**), Respiratory distress (16d - Fatal - **Results in Death**), Unresponsive to stimuli (16d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23616 | click or scan EU-EC-10007423721 | | 2021-01-25 | Healthcare Professional | EEA | Not Specified | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **23617** | click or scan EU-EC-10007423313 | | 2021-01-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23618** | click or scan EU-EC-10007423267 | | 2021-01-25 | Healthcare Professional | EEA | More than 85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash macular (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **23619** | click or scan EU-EC-10007423215 | | 2021-01-25 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **23620** | click or scan EU-EC-10007423159 | | 2021-01-25 | Healthcare Professional | EEA | More than 85 Years | Female | Dysphoria (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (0d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **23621** | click or scan EU-EC-10007422892 | | 2021-01-25 | Healthcare Professional | EEA | Not Specified | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Diabetic complication (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23622** | click or scan EU-EC-10007422755 | | 2021-01-25 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23623** | click or scan EU-EC-10007422470 | | 2021-01-25 | Healthcare Professional | EEA | More than 85 Years | Female | Agitation (2d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23624** | click or scan EU-EC-10007422172 | | 2021-01-25 | Healthcare Professional | EEA | More than 85 Years | Female | Hypoglycaemia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23625** | click or scan EU-EC-10007421999 | | 2021-01-25 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **23626** | click or scan EU-EC-10007421334 | | 2021-01-25 | Healthcare Professional | EEA | More than 85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23627 | click or scan EU-EC-10007421200 |  | 2021-01-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23628 | click or scan EU-EC-10007421187 |  | 2021-01-25 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23629 | click or scan EU-EC-10007420566 |  | 2021-01-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Coma scale abnormal (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Head injury (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Hypothermia (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Lung consolidation (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23630 | click or scan EU-EC-10007420216 |  | 2021-01-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Heart rate increased (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23631 | click or scan EU-EC-10007419556 |  | 2021-01-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23632 | click or scan EU-EC-10007416594 |  | 2021-01-23 | Healthcare Professional | EEA | More than 85 Years | Female | Hypotension (1d - Fatal - **Results in Death**), Increased bronchial secretion (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23633 | click or scan EU-EC-10007416329 |  | 2021-01-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**), Erythema (n/a - Unknown - ), Feeling hot (n/a - Unknown - ), Swelling (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23634 | click or scan EU-EC-10007414973 |  | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (4d - Fatal - **Results in Death**, Life Threatening), Hypotension (2d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23635 | click or scan EU-EC-10007411431 |  | 2021-01-22 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (0d - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23636 | click or scan EU-EC-10007411430 |  | 2021-01-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23637 | click or scan EU-EC-10007411429 | | 2021-01-22 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23638 | click or scan EU-EC-10007410192 | | 2021-01-22 | Healthcare Professional | EEA | 18-64 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23639 | click or scan EU-EC-10007407904 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Coronavirus infection (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23640 | click or scan EU-EC-10007407835 | | 2021-01-22 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23641 | click or scan EU-EC-10007407761 | | 2021-01-22 | Healthcare Professional | EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Infective exacerbation of chronic obstructive airways disease (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23642 | click or scan EU-EC-10007406874 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (2d - Fatal - **Results in Death**, Life Threatening), Cardiac failure (2d - Fatal - **Results in Death**, Life Threatening), Hyperpyrexia (2d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23643 | click or scan EU-EC-10007405602 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (8d - Fatal - **Results in Death**), Disturbance in attention (8d - Fatal - **Results in Death**), Epilepsy (8d - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), General physical condition abnormal (n/a - Fatal - **Results in Death**), Hypercalcaemia (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23644 | click or scan EU-EC-10007405344 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Male | General physical condition abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23645 | click or scan EU-EC-10007405223 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23646 | click or scan EU-EC-10007404543 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23647 | click or scan EU-EC-10007404276 | | 2021-01-22 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23648 | click or scan EU-EC-10007404231 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23649 | click or scan EU-EC-10007403867 | | 2021-01-22 | Healthcare Professional | EEA | 18-64 Years | Male | General physical condition abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23650 | click or scan EU-EC-10007403754 | | 2021-01-22 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (0d - Fatal - **Results in Death**), Decreased appetite (0d - Fatal - **Results in Death**), Diet refusal (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23651 | click or scan EU-EC-10007403602 | | 2021-01-22 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23652 | click or scan EU-EC-10007403462 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23653 | click or scan EU-EC-10007403183 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23654 | click or scan EU-EC-10007403048 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23655 | click or scan EU-EC-10007403036 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), No adverse event (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23656 | click or scan EU-EC-10007401669 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23657 | click or scan EU-EC-10007399673 | | 2021-01-22 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23658 | click or scan EU-EC-10007399016 | | 2021-01-21 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [0d - .3mL - Intramuscular]) |
| 23659 | click or scan EU-EC-10007398019 | | 2021-01-21 | Healthcare Professional | EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Agitation (1d - Fatal - **Results in Death**), Amnesia (1d - Fatal - **Results in Death**), Cardiovascular disorder (1d - Fatal - **Results in Death**), Confusional state (1d - Fatal - **Results in Death**), Disorientation (1d - Fatal - **Results in Death**), General physical health deterioration (1d - Fatal - **Results in Death**), Hypovolaemic shock (1d - Fatal - **Results in Death**), Intestinal ischaemia (1d - Fatal - **Results in Death**), Liver function test abnormal (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Metabolic acidosis (1d - Fatal - **Results in Death**), Nervous system disorder (1d - Fatal - **Results in Death**), Patient elopement (1d - Fatal - **Results in Death**), Presyncope (1d - Fatal - **Results in Death**), Renal disorder (1d - Fatal - **Results in Death**), Septic shock (1d - Fatal - **Results in Death**), Staring (1d - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 23660 | click or scan EU-EC-10007397576 | | 2021-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23661 | click or scan EU-EC-10007397256 | | 2021-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23662 | click or scan EU-EC-10007396267 | | 2021-01-21 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Arrhythmia supraventricular (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Cognitive disorder (n/a - Not Recovered/Not Resolved - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Depressed level of consciousness (n/a - Recovered/Resolved - **Results in Death**), Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**), Fall (n/a - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) |
| 23663 | click or scan EU-EC-10007395706 | | 2021-01-21 | Healthcare Professional | EEA | More than 85 Years | Male | Blood lactic acid increased (6d - Fatal - **Results in Death**), Cardiovascular disorder (6d - Fatal - **Results in Death**), Coagulopathy (6d - Fatal - **Results in Death**), Haemoglobin decreased (6d - Fatal - **Results in Death**), Hypovolaemic shock (6d - Fatal - **Results in Death**), Rectal haemorrhage (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| 23664 | click or scan EU-EC-10007393871 | | 2021-01-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - ), Cough (n/a - Not Recovered/Not Resolved - ), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23665 | click or scan EU-EC-10007392039 | | 2021-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) |
| 23666 | click or scan EU-EC-10007391673 | | 2021-01-21 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23667 | click or scan EU-EC-10007389955 |  | 2021-01-20 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23668 | click or scan EU-EC-10007389587 |  | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Male | Intestinal ischaemia (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 23669 | click or scan EU-EC-10007389528 |  | 2021-01-20 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| 23670 | click or scan EU-EC-10007389407 |  | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | Peripheral ischaemia (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 23671 | click or scan EU-EC-10007388596 |  | 2021-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Lower respiratory tract infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23672 | click or scan EU-EC-10007386908 |  | 2021-01-20 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23673 | click or scan EU-EC-10007384843 |  | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - **Results in Death**), Diarrhoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vomiting (2d - Not Recovered/Not Resolved - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23674 | click or scan EU-EC-10007384561 |  | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| 23675 | click or scan EU-EC-10007381613 |  | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23676 | click or scan EU-EC-10007381081 |  | 2021-01-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Unknown - ), Haematemesis (n/a - Fatal - **Results in Death**), Illness (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23677 | click or scan EU-EC-10007381022 | | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Male | Hyperpyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23678 | click or scan EU-EC-10007380982 | | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23679 | click or scan EU-EC-10007380914 | | 2021-01-20 | Healthcare Professional | EEA | More than 85 Years | Female | Hyperpyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23680 | click or scan EU-EC-10007380408 | | 2021-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acidosis (n/a - Not Recovered/Not Resolved - ), Blood lactic acid increased (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hemiparesis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Right ventricular enlargement (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23681 | click or scan EU-EC-10007380406 | | 2021-01-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23682 | click or scan EU-EC-10007378685 | | 2021-01-19 | Healthcare Professional | EEA | More than 85 Years | Female | Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23683 | click or scan EU-EC-10007378621 | | 2021-01-19 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory distress (5d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (12d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (12d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (12d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 23684 | click or scan EU-EC-10007378130 | | 2021-01-19 | Healthcare Professional | EEA | More than 85 Years | Female | Fluid intake reduced (n/a - Unknown - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| 23685 | click or scan EU-EC-10007377566 | | 2021-01-19 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23686 | click or scan EU-EC-10007377560 | | 2021-01-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23687 | click or scan EU-EC-10007377220 | | 2021-01-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Lower respiratory tract infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23688 | click or scan EU-EC-10007376976 | | 2021-01-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23689 | click or scan EU-EC-10007376516 | | 2021-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Livedo reticularis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Peripheral coldness (n/a - Fatal - **Results in Death**), Respiratory rate increased (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous]) |
| 23690 | click or scan EU-EC-10007376329 | | 2021-01-19 | Healthcare Professional | EEA | More than 85 Years | Female | Fatigue (3d - Fatal - **Results in Death**), General physical health deterioration (3d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23691 | click or scan EU-EC-10007376269 | | 2021-01-19 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 23692 | click or scan EU-EC-10007376224 | | 2021-01-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23693 | click or scan EU-EC-10007375382 | | 2021-01-19 | Healthcare Professional | EEA | More than 85 Years | Female | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23694 | click or scan EU-EC-10007375223 | | 2021-01-19 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23695 | click or scan EU-EC-10007375096 | | 2021-01-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23696 | click or scan EU-EC-10007374218 | | 2021-01-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23697 | click or scan EU-EC-10007372842 | | 2021-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23698 | click or scan EU-EC-10007372833 | | 2021-01-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23699 | click or scan EU-EC-10007372483 | | 2021-01-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Hyperpyrexia (4d - Fatal - **Results in Death**, Life Threatening), Respiratory distress (4d - Fatal - **Results in Death**, Life Threatening), Unresponsive to stimuli (4d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23700 | click or scan EU-EC-10007368196 | | 2021-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 23701 | click or scan EU-EC-10007368121 | | 2021-01-18 | Non Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| 23702 | click or scan EU-EC-10007367303 | | 2021-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]) |
| 23703 | click or scan EU-EC-10007366983 | | 2021-01-18 | Healthcare Professional | EEA | 65-85 Years | Female | Depressed level of consciousness (1d - Fatal - **Results in Death**), Diarrhoea (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23704 | click or scan EU-EC-10007366245 | | 2021-01-18 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (1d - Fatal - **Results in Death**, Life Threatening), Diet refusal (8d - Fatal - **Results in Death**, Life Threatening), Pneumonia (1d - Fatal - **Results in Death**, Life Threatening), Tachycardia (1d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23705 | click or scan EU-EC-10007366128 | | 2021-01-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening), Renal failure (n/a - Fatal - **Results in Death**, Life Threatening), Tachyarrhythmia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23706 | click or scan EU-EC-10007365844 | | 2021-01-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (7d - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (7d - Fatal - **Results in Death**), Pulmonary sepsis (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23707 | click or scan EU-EC-10007364938 | | 2021-01-18 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23708 | click or scan EU-EC-10007364687 | | 2021-01-18 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| 23709 | click or scan EU-EC-10007363795 | | 2021-01-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pulse absent (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 23710 | click or scan EU-EC-10007363168 | | 2021-01-17 | Healthcare Professional | EEA | More than 85 Years | Female | Pyrexia (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| 23711 | click or scan EU-EC-10007362997 | | 2021-01-17 | Healthcare Professional | EEA | More than 85 Years | Female | Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Feeling hot (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23712 | click or scan EU-EC-10007362992 | | 2021-01-17 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23713 | click or scan EU-EC-10007361020 | | 2021-01-15 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23714 | click or scan EU-EC-10007360918 | | 2021-01-15 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23715 | click or scan EU-EC-10007360900 | | 2021-01-15 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| 23716 | click or scan EU-EC-10007360893 | | 2021-01-15 | Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| 23717 | click or scan EU-EC-10007359848 | | 2021-01-15 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23718 | click or scan EU-EC-10007359067 | | 2021-01-15 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (6d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (6d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23719** | click or scan EU-EC-10007357461 | | 2021-01-15 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac fibrillation (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**), Vomiting (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **23720** | click or scan EU-EC-10007356588 | | 2021-01-15 | Healthcare Professional | EEA | 18-64 Years | Female | Huntington's disease (0d - Fatal - **Results in Death**), Seizure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| **23721** | click or scan EU-EC-10007355932 | | 2021-01-15 | Healthcare Professional | EEA | More than 85 Years | Female | Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| **23722** | click or scan EU-EC-10007355213 | | 2021-01-15 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acidosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Acute kidney injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diabetes mellitus inadequate control (1d - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23723** | click or scan EU-EC-10007355209 | | 2021-01-15 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23724** | click or scan EU-EC-10007349774 | | 2021-01-14 | Healthcare Professional | Non EEA | Not Specified | Not Specified | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **23725** | click or scan EU-EC-10007349769 | | 2021-01-14 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23726** | click or scan EU-EC-10007348967 | | 2021-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a]) |
| **23727** | click or scan EU-EC-10007347050 | | 2021-01-14 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **23728** | click or scan EU-EC-10007346524 | | 2021-01-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23729 | click or scan EU-EC-10007347612 | | 2021-01-13 | Healthcare Professional | EEA | More than 85 Years | Female | Acute respiratory failure (2d - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23730 | click or scan EU-EC-10007347608 | | 2021-01-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Headache (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Presyncope (1d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Vaccination complication (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23731 | click or scan EU-EC-10007347342 | | 2021-01-13 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 23732 | click or scan EU-EC-10007347302 | | 2021-01-13 | Healthcare Professional | EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23733 | click or scan EU-EC-10007346083 | | 2021-01-13 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23734 | click or scan EU-EC-10007344737 | | 2021-01-13 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Urinary retention (0d - Recovered/Resolved - ), Vaginal discharge (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1 {DF} - n/a]) |
| 23735 | click or scan EU-EC-10007343848 | | 2021-01-13 | Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23736 | click or scan EU-EC-10007339366 | | 2021-01-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23737 | click or scan EU-EC-10007338842 | | 2021-01-12 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23738 | click or scan EU-EC-10007337129 | | 2021-01-12 | Healthcare Professional | EEA | More than 85 Years | Male | Respiration abnormal (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23739 | click or scan EU-EC-10007335395 | | 2021-01-12 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| 23740 | click or scan EU-EC-10007333563 | | 2021-01-12 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 23741 | click or scan EU-EC-10007332244 | | 2021-01-11 | Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 23742 | click or scan EU-EC-10007331262 | | 2021-01-11 | Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 23743 | click or scan EU-EC-10007329378 | | 2021-01-11 | Healthcare Professional | EEA | More than 85 Years | Male | Dementia of the Alzheimer's type, with delirium (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| 23744 | click or scan EU-EC-10007322669 | | 2021-01-08 | Healthcare Professional | EEA | 65-85 Years | Male | Coma (n/a - Unknown - **Results in Death**, Life Threatening), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening), Flushing (n/a - Unknown - **Results in Death**, Life Threatening), Hemiparesis (n/a - Unknown - **Results in Death**, Life Threatening), Mobility decreased (n/a - Unknown - **Results in Death**, Life Threatening), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 23745 | click or scan EU-EC-10007318464 | | 2021-01-08 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| 23746 | click or scan EU-EC-10007316092 | | 2021-01-07 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Hypersensitivity (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 23747 | click or scan EU-EC-10007316044 | | 2021-01-07 | Healthcare Professional | EEA | More than 85 Years | Female | Rectal haemorrhage (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]), [ACENOCOUMAROL] (S - Atrial fibrillation - Drug withdrawn - [3203d - n/a - Oral]) |
| 23748 | click or scan EU-EC-10007315627 | | 2021-01-07 | Healthcare Professional | EEA | More than 85 Years | Male | Aggression (n/a - Unknown - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Rales (n/a - Unknown - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 23749 | click or scan EU-EC-10007314728 | | 2021-01-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 23750 | click or scan EU-EC-10007314324 | | 2021-01-07 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac failure (0d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23751 | click or scan EU-EC-10007313051 | | 2021-01-07 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 23752 | click or scan EU-EC-10007308259 | | 2021-01-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| 23753 | click or scan EU-EC-10007307981 | | 2021-01-06 | Healthcare Professional | EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 23754 | click or scan EU-EC-10007302723 | | 2021-01-05 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| 23755 | click or scan EU-EC-10007298416 | | 2021-01-05 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 23756 | click or scan EU-EC-10007293100 | | 2021-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| 23757 | click or scan EU-EC-10007292008 | | 2021-01-04 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |
| 23758 | click or scan EU-EC-10007291936 | | 2021-01-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Influenza like illness (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **23759** | click or scan EU-EC-10007276795 | | 2020-12-30 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (0d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) COMIRNATY [TOZINAMERAN] (S - SARS-CoV-2 test positive - Not applicable - [n/a - .3mL - Intramuscular]) |
| **23760** | click or scan EU-EC-10007255731 | | 2020-12-25 | Healthcare Professional | EEA | 18-64 Years | Male | Dizziness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Haematemesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23761** | click or scan EU-EC-10007255625 | | 2020-12-25 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **23762** | click or scan EU-EC-10007250183 | | 2020-12-24 | Healthcare Professional | EEA | 65-85 Years | Female | Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **23763** | click or scan EU-EC-10007249906 | | 2020-12-24 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **23764** | click or scan EU-EC-10007249776 | | 2020-12-24 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **23765** | click or scan EU-EC-10007242026 | | 2020-12-23 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - **Results in Death**), Epistaxis (n/a - Unknown - **Results in Death**), Haematemesis (n/a - Unknown - **Results in Death**), Haemoptysis (n/a - Unknown - **Results in Death**), Headache (n/a - Unknown - **Results in Death**) | [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **23766** | click or scan EU-EC-10007242008 | | 2020-12-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a]) |